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OVERVIEW

Founded in January 2015, we are an early cancer detection company with a strategic focus on high-incidence, high-mortality cancers. We have pioneered the development of methylation-based early cancer detection products. As of the Latest Practicable Date, we had two Core Products, IHepcomf (艾馨甘) and IUriSure (艾光樂), targeting liver cancer and urothelial cancer, respectively. IHepcomf (艾馨甘) is the world’s first methylation-based liver cancer early detection assay utilizing qPCR technology, demonstrating 92.33% sensitivity and 93.35% specificity in liver cancer detection through blood samples, with remarkable 84.43% sensitivity in stage I patients. Our another Core Product, IUriSure (艾光樂), offers non-invasive detection of urothelial cancer using only 1mL of urine sample, significantly improving efficiency and convenience compared to conventional methods.

We operate in the oncology molecular testing market in China. In 2024, liver cancer ranks fourth in incidence and second in cancer-related mortality in China, while urothelial cancer is characterized by its high-recurrence nature, according to Frost & Sullivan. Early detection of these cancers can dramatically improve survival rates while reducing healthcare costs associated with late-stage treatment. Although oncology molecular testing in China is still in its early stages with low penetration, it is growing rapidly according to Frost & Sullivan. The oncology molecular testing market in China has grown from RMB4.3 billion in 2019 to RMB8.7 billion in 2024, with a CAGR 15.2%, and is expected to reach RMB38.8 billion by 2033, with a CAGR of 18.1% from 2024 to 2033, according to Frost & Sullivan.

To capitalize on this market opportunity and address the early cancer detection demands in China, we have developed an integrated cancer detection platform with multiple competitive advantages. Our platform features a rich product pipeline addressing clinical needs through a portfolio of approved and development-stage products across major cancer types, including colorectal, liver and esophageal cancers, with further expansion into urothelial, gastric, lung and gynecologic cancers, among others. We are also actively expanding our pan-cancer pipeline, with a six-high-incidence-cancer combined detection panel currently under development. We employ real-time quantitative polymerase chain reaction (“qPCR”) technology, which is powered by our proprietary Intelligent Tumor Biomarker Finder (“iTBFinder”) platform built on data from cancer patients, complemented by technologies like Amplification Selective Capture (“AS-Cap”) and Sensitivity Enhanced Methylation PCR (“SEM-PCR”) that significantly enhance detection capabilities.

To address key downstream scalability challenges, we are also developing AMStation, a fully automated sample processing workstation that is designed to process up to 60 fecal samples for pre-treatment and extract and transform 16 nucleic acid samples within approximately three hours, streamlining operations and supporting large-scale testing. AMStation has completed the EMC test and safety compliance test and is expected to submit its Class I medical device filing application to the Administration for Market Regulation of Wuhan City, Hubei Province by April 2026.

As we build our pipeline, we have established an integrated early cancer detection platform with comprehensive research and development, clinical development and commercialization capabilities.

- Research and development. Our R&D capabilities are demonstrated by our proprietary technologies and platform. We have built iTBFinder, a proprietary biomarker selection platform built on over 210,000 multi-omics data entries from 13,800 cancer patients’ samples across 22 cancer types. The data utilized by the iTBFinder platform are primarily derived from publicly available biomedical databases. These include 10,394 methylation chip datasets from The Cancer Genome Atlas (TCGA), 216,031 data entries from 1,640 methylation chip datasets. The TCGA methylation data are sourced

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from the publicly accessible U.S. Cancer Genome Atlas database, while the GEO datasets comprise research data contributed by scientists worldwide. We collect, integrate, and standardize these public datasets to build a consolidated database, which forms the foundation of the iTB Finder platform and supports our biomarker discovery and validation processes.

Leveraging multi-omics data and advanced AI algorithms such as Random Forest and XGBoost, iTB Finder enables efficient identification and validation of clinically relevant biomarkers, thereby accelerating clinical product development. Our proprietary technologies also include AS-Cap and SEM-PCR that significantly improve the performance of our assays. The AS-Cap technology increases capture efficiency, while SEM-PCR increases intensity of detection signals by more than tenfold. As of the Latest Practicable Date, we ranked first in China’s early cancer detection sector in terms of the number of Class III medical device registrations, according to Frost & Sullivan.

- *Clinical development.* While our first product took more than five and a half years to develop, we have successfully reduced the average R&D cycle to four and a half years, with IHepcomf (艾馨甘) developed within a period of four years and four months, establishing a significant barrier to entry for potential competitors. Our Core Product IHepcomf (艾馨甘) demonstrated 92.33% sensitivity and 93.35% specificity in liver cancer detection through blood samples, with remarkable 84.43% sensitivity in stage I patients. As the world’s first methylation-based liver cancer assay utilizing qPCR technology, it enables early intervention and improved survival outcomes. In addition, IColohunter (艾長健), our blood-based colorectal cancer test achieves 91.42% sensitivity for colorectal cancer, 44.16% sensitivity for advanced adenomas, 73.53% for high-grade intraepithelial neoplasia, and 91.74% specificity, making it the only NMPA-approved blood-based colorectal cancer test with both sensitivity and specificity exceeding 90.00%.
- *Commercialization.* We have built a robust sales and distribution network of our products, through which our products are penetrated and/or widely adopt in the following scenarios: (i) public hospitals such as Peking Union Medical College Hospital (北京協和醫院) and over 100 other public hospitals across China; (ii) medical testing laboratories including KingMed Medical (金域醫學); (iii) major private health checkup centers like iKang (愛康國賓); and (iv) overseas distribution channels with multiple products successfully registered internationally.

OUR COMPETITIVE STRENGTHS

We believe that the following strengths have contributed to our success and differentiated us from our competitors.

Focusing on Methylation-Based Early Cancer Detection Products in China

We are an early cancer detection company with a strategic focus on high-incidence, high-mortality cancers. Our early cancer detection products aim to facilitate early diagnosis and timely intervention, which can significantly improve cure rates or survival rates, while effectively reducing the substantial treatment costs typically incurred at later stages. We offer a portfolio of approved and development-stage products across major cancer types, including colorectal, liver and esophageal cancers, with further expansion into urothelial, gastric, lung and gynecologic cancers, among others, and pan-cancer detection. Our cancer detection products are built on qPCR, a highly cost-effective and widely accessible platform. Benefiting from widespread equipment availability which facilitates rapid adoption and easy reagent distribution, qPCR becomes an ideal technology for large-scale early cancer detection programs. In addition,

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our modified qPCR technologies enable accurate detection at the single cell level. Furthermore, our experience in successfully developing early detection products has enabled us to expand our minimal residual disease (“MRD”) recurrence monitoring, with the aim of achieving full-scenario coverage from early detection to recurrence monitoring.

We have pioneered multi-sample compatibility across blood, stool, urine and cell specimens, significantly minimizing invasiveness and enhancing patients’ acceptance. Our IUriSure (艾光樂) test for urothelial cancer requires only 1mL of urine sample, a significant improvement over competing products that typically require more than 50mL of urine sample, thereby reducing logistical burden and improving user convenience. Similarly, our colorectal cancer detection products IColoComf (艾長康) and IColoHunter (艾長健) use stool and blood samples to accurately detect intestinal lesions. This non-invasive method avoids the discomfort and risks of colonoscopy, such as bloating, pain, mucosal injury, bleeding, perforation, infection, and anesthesia side effects. It is especially suitable for elderly, frail, or early detection products cardiovascular patients who may not tolerate colonoscopy. Our colorectal cancer detection products protect patient privacy and improve acceptance.

As of the Latest Practicable Date, we held five Class III medical device registrations, ranking first in the early cancer detection sector in China, and 82 registered patents. Our approved and commercialized products include tests for colorectal, esophageal, urothelial and liver cancers, and we are further developing recurrence monitoring products for liver cancer and urothelial cancer. We are also actively expanding our pan-cancer pipeline, with a six-high-incidence-cancer combined detection panel currently under development, aimed at improving early detection across multiple cancer types and supporting eventual market launch.

To address key downstream scalability challenges, we are also developing AMStation, a fully automated sample processing workstation that is designed to process up to 60 fecal samples for pre-treatment and extract and transform 16 nucleic acid samples within approximately three hours, streamlining operations and supporting large-scale testing. AMStation has completed the EMC test and safety compliance test and is expected to submit its Class I medical device filing application to the Administration for Market Regulation of Wuhan City, Hubei Province by April 2026.

Our growth is turbocharged by China’s cancer prevention policies, particularly the *Healthy China 2030* which targets a 55%+ early diagnosis rate for high-incidence cancers by 2030. The oncology molecular testing market in China has grown from RMB4.3 billion in 2019 to RMB8.7 billion in 2024, with a CAGR 15.2%, and is expected to reach RMB38.8 billion by 2033, with a CAGR of 18.1% from 2024 to 2033, according to Frost & Sullivan. Late-stage cancer treatment costs over 10 times more than early interventions, imposing crippling burdens on families and the healthcare system.

First Early Liver Cancer Test Utilizing qPCR Technology and Non-Invasive Urine-Based Early Urothelial Cancer Test

Our two Core Products, IHepcomf (艾馨甘) and IUriSure (艾光樂), focus on liver cancer and urothelial cancer, respectively.

According to Frost & Sullivan, our Core Product IHepcomf (艾馨甘) is the world’s first methylation-based liver cancer assay utilizing qPCR technology. IHepcomf (艾馨甘) demonstrated 92.33% sensitivity and 93.35% specificity in liver cancer detection through blood samples, with 84.43% sensitivity in stage I patients, enabling early intervention and improved survival outcomes. Leveraging proprietary DMLT, IHepcomf (艾馨甘) identifies an optimal panel of biomarkers specifically suited for blood-based detection of liver cancer. The test utilizes a specialized cfDNA extraction and conversion reagent kit developed in-house for plasma samples to sensitively detect trace amounts of ctDNA within cfDNA. We are also

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advancing the development of an MRD test for liver cancer recurrence monitoring, forming a full-cycle solution from early detection to post-treatment surveillance.

IUrisure (艾光樂) is a non-invasive urine-based assay designed for the early detection of urothelial cancer, a cancer characterized by its high recurrence rate. The product employs novel methylation biomarkers AL021918.2 gene and VIM gene, enabling high sensitivity and specificity. IUrisure (艾光樂) has successfully obtained NMPA registration as a Class III medical device in October 2025. IUrisure (艾光樂) offers exceptional sample efficiency and convenience. It requires only 1mL of urine sample, significantly less than the 50mL typically required by peer products. This sample efficiency reduces transportation costs and enhances downstream clinical adoption. Validated in 1,571 clinical samples, IUrisure (艾光樂) demonstrated excellent performance with a sensitivity of 92.94% and a specificity of 92.83%. The test shows sensitivity above 90.00% across multiple urothelial cancer subtypes.

Liver and urothelial cancers collectively represent a significant global health burden. Liver cancer ranks sixth globally in incidence and third in cancer-related mortality, its impact is even more pronounced in China, where it ranks fourth and second, respectively. Early-stage liver cancer typically presents no obvious symptoms, yet can be treated effectively with minimally invasive surgery, significantly improving survival rates compared to late-stage diagnosis. Urothelial cancer is characterized by its high-recurrence nature, with early detection in high-risk populations dramatically improving prognosis. Both indications suffer low compliance from participants due to the invasiveness of conventional methods, such as biopsies and cystoscopy. Other conventional testing methods such as imaging and AFP (alpha-fetoprotein) testing for liver cancer have limited sensitivity for early-stage cancer detection. Our non-invasive tests with high sensitivity address these problems, offering substantial market potential in both domestic and international settings.

In addition, despite the mass population recommended for liver cancer and urothelial cancer early detection, the penetration rate among such population is low in China, with 0.7% for liver cancer in 2024 and 0.5% for urothelial cancer in 2024. The shortcoming of conventional testing methods combined with the comparatively low detection penetration rates in China highlight a significant market opportunity.

Strong R&D and Industrialization Capabilities with Proven Track Record of Success

Leveraging multidisciplinary technology integration, our technology platform centers on AI-driven DNA methylation biomarker discovery combined with liquid biopsy molecular diagnostics. This platform is designed to identify critical early cancer detection markers and translate them into clinical actionable products.

Since our inception, we have focused on the discovery of key biomarkers for early cancer detection and have built a proprietary biomarker selection platform, iTBFinder, built on over 210,000 multi-omics data entries from 13,800 cancer patients’ samples across 22 cancer types, iTBFinder integrates DNA methylation and transcriptomic data to power out continuous pipeline expansion. Leveraging our tumor genome evolution simulation algorithm grounded in multi-omics data and tumor evolution theory and other advanced AI algorithms such as Random Forest and XGBoost, iTBFinder enables efficient identification and validation of clinically relevant biomarkers. In addition, iTBFinder includes a user-friendly, interactive web interface that enables our R&D team to research, visualize, and review biomarker performance and underlying omics evidence in real time. Please refer to “ – Research and Development – Technology Platforms” in this section. Based on this platform, five early detection products have completed a full “discovery-to-commercialization” cycle, which encompasses technology exploration, clinical translation, validation, regulatory submission and scalable production, reducing the average R&D cycle to four and a half years and establishing a significant barrier to entry for potential competitors.

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Our technology platform is further reinforced by the integration of two proprietary general-purpose technologies: AS-Cap and SEM-PCR, which together significantly improve the overall performance and scalability of our methylation-based assays. Our AS-Cap technology uses competitive capture probe design to avoid non-specific binding to bacterial and dietary DNA, which accounts for over 99.99% of stool samples, enabling highly specific capture of human DNA fragments. This technology increases capture efficiency and reduces the required sample volume to within a 2 mL microcentrifuge tube, greatly improving convenience for large-scale processing. Our SEM-PCR technology leverages the unique characteristics of bisulfite-converted DNA, where double-stranded sequences are no longer complementary and methylation status differs between strands. By integrating multiple primer design with tandem probe technology, SEM-PCR generates multiple fluorescence signals from each amplified DNA molecule in every PCR cycle, boosting intensity of detection signals by more than tenfold, allowing identification of low-abundance methylation targets and overcoming the inefficiency of traditional PCR caused by strand methylation asynchrony and signal dilution.

Proven Commercialization Model with Scalable Distribution Network

The successful market launch of IColocomf (艾長康), IColohunter (艾長健), IEsohunter (艾思寧) and IHepcomf (艾馨甘) demonstrates our commercialization capabilities. We have built a robust commercialization infrastructure with an sales and distribution network spanning medical testing laboratories and private health checkup centers and distributors whose downstream customers include public hospitals and primary-level healthcare institutions. We have formed strategic collaborations with a number of well-established medical testing laboratories across China, which we believe enhances our market reach, especially in scenarios involving physician referrals and diagnostic workflows. These laboratories play a critical role in expanding the accessibility and clinical adoption of our products by integrating them into their routine testing services. Medical testing laboratories we collaborate with include KingMed Medical (金域醫學). We have established solid business collaborations with leading health checkup centers across China, which we believe enables us to fast penetrate the market with a well-developed end-user base and to promote market acceptance of our early cancer detection products. Health checkup centers also benefit from the convenience and high efficacy of our products. For example, we have promoted our products at iKang (愛康國賓), one of the largest health checkup center chains in China. Our network also encompass public hospitals such as Peking Union Medical College Hospital (北京協和醫院) and primary-level healthcare pilot programs in Henan, Hebei, Hubei and Liaoning.

Beyond China, we have secured a foothold in over 30 countries, including the UK, Middle East, and Africa, leveraging our 12 CE-IVD Mark and six UK MHRA approvals. Strategic partnerships with global giants like HybriBio Biotech further enhanced our credibility in regulated markets.

Experienced Leadership and Strong Investor Backing

Our management team comprises top-tier industry veterans with deep expertise in oncology diagnostics, molecular biology, regulatory strategy, and commercialization. With dual backgrounds in clinical research and hospital operations, they provide strategic insight into cancer detection program adoption.

We have a strong in-house research and development team of 40 members primarily based in Wuhan, Hubei Province, PRC as of the December 31, 2025, with 65.0% holding a bachelor's degree or higher. Our founder and Chairman, Dr. Zhang Lianglu, holds a PhD and is a senior engineer with leadership and academic credentials. He is an alumnus of CEIBS and Harvard Business School HBX. Dr. Zhang also serves in multiple advisory and executive roles in professional and academic organizations, including executive vice president of the Wuhan University Economics and Management Alumni Association (武漢大學經管分會常務副會長),

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director of the Wuhan University Entrepreneurs Association (武漢大學校友企業家聯誼會理事), member of the Gastric Cancer Biomarker Collaborative Group under the Tumor Marker Professional Committee of the China Anti-Cancer Association (中國抗癌協會腫瘤標誌專業委員會胃癌標誌物協作組委員). Our co-founder, Dr. Dong, holds a PhD degree, is a senior engineer, and an Optics Valley 3551 Innovation Talent (光谷3551創新人才). She is an alumna of CEIBS and Fosun Star Future Academy (FOSUN星未來研究院). Dr. Dong joined our Company in 2016, where she served as R&D president, and since 2021 has been vice general manager of R&D and Manufacturing while continuing as R&D president. Dr. Dong has led the establishment of our early cancer detection and diagnostic technology platforms, completed the development of multiple cancer detection products, published over 10 SCI papers, and filed more than 100 invention patents. Supporting Dr. Dong and leading our R&D the team is Mr. Wu Zhicheng (吳志誠), our Chief Information Officer, who previously served as a professor at Westlake University (西湖大學). He participated in international collaborative studies on breast and thyroid cancers, developed a widely recognized multi-label algorithm, and has authored over a dozen SCI papers with more than 2,800 citations. He also holds numerous patents and has received two first prizes for Scientific and Technological Achievements and one second prize for Natural Science in Jiangxi Province. Supporting Dr. Dong and Mr. Wu are our three R&D deputy directors. Dr. Zhou Dihan (周諦晗), our Chief Technology Officer who brought nearly a decade of experience from the CAS Wuhan Institute of Virology, where she led National Natural Science Foundation projects and published more than 20 SCI papers. Dr. Guo Hong (郭洪), who earned her doctorate from Huazhong Agricultural University (華中農業大學) and spent nine years at the CAS Wuhan Institute of Virology, specializing in virology and immunology. She led two NSFC projects, published 24 papers, and holds over 20 patents and patent applications. Finally, Dr. Zhou Jun (周俊), who managed NSFC projects and international collaborations, authoring multiple SCI papers and securing more than 30 patents. Together, our R&D team combines expertise with a strong track record of innovation and scientific excellence.

Our continued growth is also supported by institutional and industrial investors, ensuring long-term financial stability and sustained innovation. We have completed six funding rounds backed by marquee investors such as CCB Investment, HybriBio Biotech, Suzhou Kinghall and Changjiang Innovation. This financial muscle supports our R&D investment and infrastructure expansion, including our ISO 13485-certified manufacturing facility in Wuhan.

OUR DEVELOPMENT STRATEGIES

We plan to execute the following strategies to achieve our mission and drive our future growth.

Expand Our R&D Capabilities and Platform to Advance Our Pipeline Products

We focus on developing technologies for early cancer detection to enhance our existing pipeline and to develop new early cancer tests. We believe that our success has stemmed from and will continue to depend on our ability to develop new or improved early cancer detection products. To support our research and development efforts, we plan to recruit additional experts to strengthen our internal research and development team, and complement our in-house research and development capabilities through collaborations with reputable domestic and international academic and medical institutions.

We are primarily engaged in R&D. For the year ended December 31, 2025, our R&D expenses amounted to RMB21.3 million representing 138.1% of its total revenue, representing an increase of 42.0% from the year ended December 31, 2024. As at December 31, 2025, our R&D team consisted of 40 employees.

We have a well-positioned pipeline of single- and multi-cancer early detection tests in early to advanced stage of development. In the near term, we plan to advance the R&D on our new

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indication of our Core Products IHepcomf (艾馨甘) and IUrisure (艾光樂) for MRD detection. We also plan to advance our pipeline products, IStomacomf (艾衛元) for gastric cancer and the IPulmocomf (艾斐暢) for lung cancers. In the long run, we aim to continuously optimize our proprietary iTBFinder platform and integrate a pre-trained large language model-based literature semantic fusion system to establish a closed loop of target discovery, validation and clinical data interpretation, thereby improving the accuracy of clinical translation and data analysis. In addition, we plan to enhance the traceability accuracy of our pan-cancer products and advance regulatory submissions and commercialization of these products in China and in EU.

We will continue to collaborate with external partners to develop and upgrade the fully automated sample processing workstation, AMStation, that supports different sample types, with the goal of achieving streamlined “sample-to-result” convenience to address downstream operational pain points. Meanwhile, we will accelerate the international registration of our Core Products, with a focus on key markets in Europe, Southeast Asia and South America.

In the disease detection and diagnostic industry, maintaining a robust and competitive product pipeline is essential for achieving sustainable commercial growth. We have therefore placed strategic emphasis on continuous R&D investment, focusing on expanding the clinical indications of our core products, including those intended for re-examination and recurrence monitoring, and advancing the clinical development of new products targeting gastric cancer, lung cancer, and multi cancer detection. The continued implementation of these R&D initiatives enhances our technological capability and supports the progressive enrichment of our product portfolio to meet increasing market demand for early cancer detection and long-term disease management.

As of the Latest Practicable Date, our core R&D and management teams remained stable, and our key technology platforms had been fully established. These factors provide a solid foundation and improve the feasibility and likelihood of success of our ongoing and future clinical development programs. With established technology platforms and experienced personnel, our product pipeline is positioned for steady advancement and to support the sustainable growth of our business operations.

Promote Early Cancer Detection and Increase Penetration of Our Products in Key Markets

We successfully commercialized our self-developed early cancer detection test, IColocomf (艾長康), IColohunter (艾長健), IEsohunter (艾思寧), IHepcomf (艾馨甘) and IUrisure (艾光樂) in 2022, 2024, 2025, 2025 and 2025, respectively. We are actively expanding our sales and marketing teams and engaging key ecosystem stakeholders including academic and clinical KOLs, key tertiary hospitals, clinical laboratories and distribution channels in preparation for a major commercial launch. We plan to prioritize promoting liver cancer detection, strengthening nationwide liver cancer awareness initiatives, focusing on esophageal cancer in high-incidence regions, and leveraging scale efficiency in colorectal cancer testing through competitive pricing.

We plan to further broaden our sales network to increase the contribution of direct sales, thereby improving our gross margin. Domestically, we will strengthen both in-hospital channels (including various tiers of public hospitals where we also aim to actively participate in the formulation of clinical diagnosis and treatment guidelines and expert consensus to promote the adoption of DNA methylation-based detection) and out-of-hospital channels (including physical examination centers, third-party laboratories, county-level medical institutions, early cancer detection platforms, and insurance companies). Internationally, we plan to expand our footprint across the EU and Southeast Asia through regulatory registration, distributor partnerships, and clinical collaborations. Tailored commercialization strategies will be adopted to address local regulatory requirements and patient needs.

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Improve Profitability and Support Future Growth by Enhancing our Manufacturing Facilities

We conduct all of the manufacturing process of our reagents and sample collection kits in-house and have manufacturing facilities located at Wuhan, China with an annual production capacity of approximately 1.3 million tests, which was primarily used for the production of our early cancer detection products and product candidates during the Track Record Period. Our manufacturing facilities are equipped with advanced automation, which can significantly improve efficiency and reduce manufacturing costs. To meet the anticipated surge in demand, we plan to establish fully automated production facilities that significantly increase our annual production capacity. These facilities will be equipped with high-throughput systems and intelligent process controls to improve productivity and ensure consistent product quality. The expanded production capacity will also support our geographic expansion strategy and enable us to introduce a broader portfolio of early cancer tests to the market.

Optimize Raw Materials and Supply Chain Management

We recognize the importance of a resilient and efficient supply chain in supporting our long-term growth and ensuring uninterrupted provision of our products and services to customers in different markets. To this end, we intend to strengthen our upstream raw material development and optimize our overall supply chain structure.

For the production of early cancer detection products and product candidates, our principal raw materials are enzymes, reagents and packaging and labeling materials. We plan to continue the in-house development of key reagents and apply iterative technological upgrades to improve transformation efficiency and ensure a secure and stable supply of key raw materials. We also aim to lower the cost of reagents through both production optimization and logistics improvements. In particular, we intend to adopt lyophilization technology to reduce transportation costs and improve product stability during long-distance distribution.

Selectively Pursue Investment, Acquisition or Partnership Opportunities to Integrate Industry Resources

We plan to complement our organic growth with prudent investment, acquisition or partnership. Particularly, we plan to opportunistically acquire product candidates which have significant market potential or technologies, complement our existing product portfolio or have synergies with our existing research and development, manufacturing and commercialization infrastructure. To pursue such opportunities, we will explore suitable investment and partnership arrangements, including establishing strategic alliances, joint ventures and in-licensing relationships. We believe that our industry knowledge and research and development expertise will not only empower us to promptly identify and capture potential targets to enrich our product portfolio but also make us a more desirable acquiror or partner than our competitors. Furthermore, our strong business execution capabilities will enable us to integrate the acquired products and/or business or assets seamlessly into our existing platform. As of the Latest Practicable Date, we did not have any specific acquisition or partnership targets, plans or a definite timeline and had not entered into any definitive agreement or engaged in any active discussion with any potential target.

OUR PRODUCT AND PRODUCT PIPELINE

We are an early cancer detection company with a strategic focus on high-incidence, high-mortality cancers. We have pioneered the development of methylation-based early cancer detection technologies. IHepcomf (艾馨甘), targeting liver cancer and approved by NMPA as a Class III medical device in January 2025, and IUrisure (艾光樂), targeting urothelial cancer and approved by NMPA as a Class III medical device in October 2025, constitute our Core Products for purposes of this document. In addition, our early cancer detection test portfolio comprises

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three other self-developed NMPA-approved products, namely, IColocomf (艾長康), IColohunter (艾長健) and IEsohunter (艾思寧), with IColocomf (艾長康) and IColohunter (艾長健) both targeting colorectal cancer and approved by NMPA as Class III medical device in 2022 and 2024, respectively, and IEsohunter (艾思寧) targeting esophageal cancer and approved by NMPA as Class III medical device in January 2025. A complete reagent kit of our products typically includes: (i) sample collection device; (ii) nucleic acid extraction reagent; (iii) conversion reagent; and (iv) PCR detection reagent.

In addition to our Core Products, we have four other product candidates, including IStomacomf (艾衛元) targeting gastric cancer, IPulmocomf (艾斐暢) targeting lung cancer, IUterasure (艾宮樂) targeting endometrial cancer and multiple cancer detection product PanCa-6 (艾露元). Our product candidates are subject to approval by relevant authorities regulating medical devices, such as NMPA, before commercialization in relevant jurisdictions. For details, please see “Regulation Overview” in this document. As confirmed by our Directors, and based on the interview with the relevant regulatory authority, our PRC Legal Advisors are of the view that, as of the Latest Practicable Date and to the best of their knowledge, they have not yet learned of any negative information that may materially delay or impede the approval of the new indication for IHepcomf (艾馨甘) or IUrisure (艾光樂).

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The following chart summarizes the development status of our products and major product candidates as of the Latest Practicable Date:

Product ⁽¹⁾	Indication	Sample Type	Early Stage Development China (Class III) EU (CE-IVD mark)	Late Stage Development ⁽²⁾	Development Stage Regional Trial	Registration/Approval obtained ⁽³⁾	Upcoming	Technology	Type	Targeted Stage of Cancer	Targeted Market / Jurisdiction	Self-Development (Yes/No)
★ Heliocent (艾博特)	Liver cancer detection	Blood	China (Class III) EU (CE-IVD mark)			NMPA approval: January 2025 EU CE-IVD mark: March 2022	N/A	PCR	Class III Medical Device	Stage I to IV	China and EU	Yes
	Liver cancer detection	Blood	China (Class III)			N/A	To submit NMPA registration application by the end of 2027	PCR	Class III Medical Device	Recurrent	China	Yes
★ HeliStar (艾美隆)	Uterine cancer	Urine	China (Class III) EU (CE-IVD mark)			NMPA approval: October 2025	To progress towards obtaining CE-IVD mark	PCR	Class III Medical Device	Stage I to IV	China and EU	Yes
	Uterine cancer MID	Urine	China (Class III)			N/A	To commence clinical trial in 2024H1	PCR	Class III Medical Device	Recurrent	China	Yes
Hismocent (艾斯隆)	Gastric cancer	Blood	China (Class III)			N/A	To commence clinical trial in 2024H1	PCR	Class III Medical Device	Stage I to IV	China	Yes
Hilacocent (艾美隆)	Lung cancer	Blood	China (Class III)			N/A	To commence clinical trial in 2024H2	PCR	Class III Medical Device	Stage I to IV	China	Yes
Hibemane (艾美隆)	Endometrial cancer	Cell	China (Class III) EU (CE-IVD mark)			EU CE-IVD mark: May 2022	To commence clinical trial in 2027H2	PCR	Class III Medical Device	Stage I to IV	China	Yes
ParC-6 (艾美隆)	Multi-Cancer (6 cancers) ⁽⁴⁾	Blood	China (Class III)			N/A	To commence clinical trial in 2027H2	PCR	Class III Medical Device	Stage I to IV	China	Yes
Heliocent (艾美隆)	Colorectal cancer	Stool	China (Class III medical device) EU (CE-IVD mark)			NMPA approval: March 2022 EU CE-IVD mark: June 2021	N/A	PCR	Class III Medical Device	Pre-cancer, Stage I to IV	China	Yes
Heliobum (艾美隆)	Colorectal cancer	Blood	China (Class III medical device) EU (CE-IVD mark)			NMPA approval: September 2024 EU CE-IVD mark: March 2022	N/A	PCR	Class III Medical Device	Pre-cancer, Stage I to IV	China	Yes
Helihunter (艾美隆)	Esophageal cancer	Blood	China (Class III medical device) EU (CE-IVD mark)			NMPA approval: January 2025 EU CE-IVD mark: March 2022	N/A	PCR	Class III Medical Device	Pre-cancer, Stage I to IV	China	Yes

★ Core Product

Notes:

- (1) All of our products and product candidates are internally-developed.
- (2) Early stage development means the development stage where a product candidate is undergoing one or more of the following: feasibility analysis, biomarker screening, development of prototype kits, and algorithm development.
- (3) Late stage development means the development stage where a product candidate is undergoing one or more of the following: small-scale performance testing, trial production, comprehensive performance evaluation and is ready for registration trials.
- (4) Include lung cancer, colorectal cancer, gastric cancer, liver cancer, esophageal cancer and pancreatic cancer
- (5) While we do not have immediate plans to engage operations and conduct sales in EU market, we have obtained an EU CE-IVD mark for all our products in our commercialized early cancer detection test portfolio as it provided a foundational regulatory milestone for our future commercialization efforts in the EU market.

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Summary of Clinical Trials

Please find below the summary of each completed, on-going and planned regulatory clinical trials. The clinical trials presented in the table below were all registration clinical trials conducted for the purpose of obtaining Class III medical device registration certificates.

Product/Indication	Sponsor	Status	Period (Start-End)	Trial Design & Key Results
IColocomf	The Company	Completed	06/2019–11/2021	SDC2 & TFPI2 kit; Sensitivity: 95.3%, Specificity: 93.5% against the clinical reference standard; High agreement with Sanger Sequencing
IColohunter	The Company	Completed	04/2022–05/2024	NTMT1 & MAP3K14 AS1 kit; Sensitivity 91.4%, Specificity: 91.7% against the clinical reference standard; High agreement with Sanger Sequencing
IEsohunter	The Company	Completed	04/2022–08/2024	KCNA3 & OTOP2 kit; Sensitivity: 87.1%, Specificity: 93.0% against the clinical reference standard; High agreement with Sanger Sequencing
IHepcomf	The Company	Completed	05/2022–08/2024	GNB4 & Riplet kit; Sensitivity: 92.3%, Specificity: 93.4% against the clinical reference standard; High agreement with Sanger Sequencing.
IUrisure	The Company	Completed	06/2023–07/2025	VIM & AL021918.2 kit; Sensitivity: 92.9%, Specificity: 92.8% against the clinical reference standard High agreement with Sanger consistency.
IHepcomf Liver cancer recurrence monitoring	The Company	Ongoing	TBD	More than 500 patients expected post resection, transplant, ablation or TACE; compare test results against clinical reference to assess recurrence detection.
IUrisure Urothelial cancer recurrence monitoring	The Company	Pre-clinical stage	TBD	Planned recurrence monitoring study.

The biomarkers and detection methods for our Core Products, IHepcomf and IUrisure, are developed based on our proprietary cancer detection technology platforms, iTBFinder and DMLT. All stages of biomarker discovery and validation were performed internally by our research and development team using publicly available databases and proprietary datasets, with no external collaborations involved.

The biomarkers selection process of IHepcomf and IUrisure are also driven by the DMLT (DNA Methylation Location Technology). DMLT enables precise identification of the specific regions within target genes that are most suitable for methylation detection. As genes are typically several thousand base pairs long with multiple methylation sites, determining the optimal detection region is critical for accuracy. In both products, DMLT was applied to locate

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and validate the most differential methylation sites, thereby enhancing the precision and reliability of the detection results.

The technologies of iTBFinder and DMLT enabled systematic screening and comparative analysis of global DNA methylation profiles to identify specific methylation markers for HCC in IHepcomf and UC in IUrsure respectively.

IHepcomf (艾馨甘) – Our Core Product

IHepcomf (艾馨甘) is our internally developed non-invasive blood-based test designed for the early detection of liver cancer. It is the world’s first early-stage liver cancer diagnostic product based on qPCR technology. Leveraging DNA Methylation Location Technology (“DMLT”), IHepcomf (艾馨甘) identifies an optimal panel of biomarkers specifically suited for blood-based detection of liver cancer. The test utilizes a specialized cell-free DNA (“cfDNA”) extraction and conversion reagent kit developed in-house for plasma samples to sensitively detect trace amounts of circulating tumor DNA (“ctDNA”) within cfDNA. We obtained the NMPA approval for Class III medical device registration for January 2025 and the CE-IVD Mark in March 2022.

Testing Process

- *Physician consultation & initial risk assessment.* When a patient presents with symptoms or imaging results suggestive of hepatic space-occupying lesions, the physician will assess their medical history and clinical background to determine whether the patient is suitable for the IHepcomf (艾馨甘) cancer detection.
- *Blood sample collection.* If the patient agrees to proceed with testing, a minimum of 10 mL of peripheral blood will be collected using either EDTA anticoagulant tubes or cfDNA preservation tubes. After gentle mixing, plasma is separated via two rounds of centrifugation to avoid cellular contamination. Then the plasma is transferred into new tubes and stored under appropriate conditions.
- *cfDNA extraction & PCR amplification.* cfDNA is extracted from plasma using dedicated nucleic acid extraction and purification reagents. The extracted cfDNA undergoes bisulfite conversion, which enables the differentiation of methylated from unmethylated sequences during PCR amplification. The bisulfite-converted cfDNA is added to a PCR reaction mix containing specific primers and fluorescent probes targeting the methylated regions of the GNB4 gene and Riplet gene, as well as the internal control gene ACTB (β -Actin). The reaction is run on a compatible real-time PCR instrument. Fluorescence signals are collected and amplification curves are analyzed to determine the presence of methylation in the target genes.
- *Risk report & follow-up.* PCR data is interpreted using defined cycle threshold (“Ct”) value thresholds and amplification curve profiles. A positive result (i.e., methylation detected in either or both GNB4 and Riplet genes) suggests a higher risk of primary liver cancer, and further clinical evaluations such as imaging or biopsy may be recommended. A negative result (i.e., no methylation detected in either gene) suggests a lower risk, though regular monitoring may still be warranted depending on the patient’s overall clinical background.

Product Development and Design

Sets forth below is a detailed timeline of the R&D progress for IHepcomf (艾馨甘):

- September 2020: commenced research and development of IHepcomf (艾馨甘).
- March 2022: obtained CE certificate for IHepcomf (艾馨甘) in Europe.

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- May 2022: obtained ethics approval from the principal clinical trial site.
- July 2022: completed the filing for registrational trial of IHepcomf (艾馨甘) with Hubei MPA.
- September 2022: commencement of clinical trial for IHepcomf (艾馨甘), with a total of 1,248 participants enrolled for the clinical efficacy study as of August 2024.
- October 2023: completed registrational trial of IHepcomf (艾馨甘).
- November 2023: submitted formal application to NMPA for IHepcomf (艾馨甘) to be registered as a Class III medical device.
- February 2024: received supplementary notice from the NMPA.
- October 2024: completed supplementary clinical trial for IHepcomf (艾馨甘).
- November 2024: submitted supplementary clinical trial documentation to NMPA.
- January 2025: obtained NMPA approval for registration as a Class III medical device.
- February to July 2025: conducted a clinical demand assessment for liver cancer recurrence monitoring and the necessity of expanding the intended use and target population of IHepcomf (艾馨甘).
- August 2025: commenced preparatory work for the recurrence monitoring clinical study and completed ethics submissions and other documentation for clinical approval.
- September 2025: held clinical trial protocol discussion meetings with PIs for the clinical trial of IHepcomf (艾馨甘) MRD detection.
- October 2025: obtained ethic approval from the lead hospital.
- November 2025: executed a collaboration agreement with the lead hospital and filed clinical trial with the Hubei Provincial Medical Products Administration (湖北省藥監局).
- December 2025: held a clinical trial initial meeting and commenced sample collection.

Development Process

Using methylation data from over 400 HCC and over 100 normal liver tissue samples from public databases, namely The Cancer Genome Atlas (“TCGA”) and Gene Expression Omnibus (“GEO”) databases, iTBFinder identified over 1,000 differentially methylated regions (“DMRs”). Publicly available data of both cancerous and healthy tissues are collected, cleaned, and integrated into iTBFinder platform, where different algorithms are applied to address the unique characteristics of each cancer type. By setting parameters based on biomarker features and performance requirements, researchers can efficiently identify the most promising biomarkers. Combining curated data, advanced algorithms, and cancer-specific parameter design, iTBFinder enables precise and efficient biomarker screening and selection.

The DMRs were further evaluated for specificity against methylation data from healthy blood cells and other cancer types within the database, yielding seven candidates of differentially methylated genes (“DMGs”) with strong HCC specificity.

To confirm these findings, whole-genome bisulfite sequencing was conducted on 12 paired HCC and adjacent normal tissue samples, identifying over 1,800 DMGs and validating the methylation patterns of the seven candidates. The ROC curve analysis of the aforementioned seven candidates was conducted using the methylation data from the tissue samples in TCGA. The results indicated that the dual-marker combination of GNB4 and Riplet achieved the highest

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diagnostic accuracy, with an AUC of 91.47% and were validated by sequencing in tissue sample, leading to the final identification of the dual-biomarker combination GNB4 and Riplet.

Multiple studies have demonstrated that the methylation of the target genes GNB4 and Riplet in IHepcomf exhibits excellent performance in liver cancer detection.

Technology

During tumor development, abnormal DNA methylation frequently occurs at CpG sites within gene promoter regions, particularly in tumor suppressor genes, leading to their transcriptional silencing. This alteration serves as a biomarker for early cancer detection.

Our IHepcomf (艾馨甘) early cancer test leverages this principle by detecting methylation changes in specific CpG regions of the GNB4 and Riplet genes, both of which are closely associated with the development of primary liver cancer. The process begins with the extraction of cfDNA from human plasma using magnetic bead-based nucleic acid purification. The purified cfDNA is then subjected to bisulfite conversion, which chemically converts unmethylated cytosines into uracils while leaving methylated cytosines unchanged. This conversion introduces sequence differences that allow us to distinguish between methylated and unmethylated DNA.

IHepcomf (艾馨甘) uses methylation-specific primers and fluorescent probes targeting the bisulfite-converted sequences of GNB4 and Riplet genes. Real-time PCR amplification is performed, with methylation detection signals captured through the FAM channel for GNB4 and the ROX channel for Riplet. Once signals are captured, the system analyzes amplification curves and Ct values to determine the presence or absence of methylation in the target genes. These results are then interpreted according to predefined thresholds, and a risk report is generated to guide subsequent clinical decisions. To ensure reliability and consistency, each test includes both positive and negative controls. An internal control gene, ACTB (β -Actin), is simultaneously amplified through the VIC channel to assess DNA quality and quantity.

Competitive Advantages

As the world’s first early-stage liver cancer diagnostic product based on qPCR technology, IHepcomf (艾馨甘) has the following advantages:

- *Advanced and proprietary technology and know-how.* Leveraging DMLT, IHepcomf (艾馨甘) identifies an optimal panel of biomarkers specifically suited for blood-based detection of liver cancer. The test utilizes a specialized cfDNA extraction and conversion reagent kit developed in-house for plasma samples to sensitively detect trace amounts of ctDNA within cfDNA. Furthermore, to overcome the challenge of low cfDNA abundance in blood, IHepcomf (艾馨甘) employs a modified qPCR technology specifically designed for cfDNA, combined with a proprietary SEM-PCR technology, which increases the intensity of detection signals by more than tenfold, enabling reliable detection of target genes at concentrations as low as 1 copy/ μ L. Please refer to “– Research and Development – Technology Platforms – SEM-PCR Technology” in this section.
- *Clinical performance.* Validated in 1,182 clinical samples, IHepcomf (艾馨甘) demonstrated a sensitivity of 92.33% and a specificity of 93.35%. For details, please refer to “– IHepcomf (艾馨甘) – Our Core Product – Summary of Clinical Trial” in this section.
- *Early detection.* IHepcomf (艾馨甘) demonstrated sensitivity of 84.43% for Stage I liver cancer, significantly outperforming traditional AFP (alpha-fetoprotein) testing.

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- *Widely accessible testing platform.* IHepcomf (艾馨甘) is compatible with widely available qPCR platforms used across medical testing institutions, without requiring specialized consumables. Sample processing steps are also adaptable to automated nucleic acid extraction instruments, enabling standardization and automation without additional costs.
- *Medical insurance coverage.* IHepcomf (艾馨甘) has already been included in the medical insurance coverage of Beijing and Shanxi province and is in the process of being incorporated into the healthcare reimbursement systems of other provinces. In Beijing, the test related to IHepcomf has been categorized as a Class A medical insurance reimbursement item. This classification indicated full reimbursement eligibility under the basic medical insurance scheme. In Shanxi province, the same test has been classified as a Class B medical insurance reimbursement item. The corresponding reimbursement policy allows for partial patient to co-payment under the provincial healthcare scheme.

There is currently no unified national reimbursement code, and most methylation-based products have not been included in the national classification and coding system for medical consumables. Local pilot programmes generally adopt a “fee-for-service” model without a unified reimbursement standard. Accordingly, inclusion under medical insurance is mainly limited to local pilot schemes, and a unified national catalogue has not yet been established.

The timing for nationwide inclusion remains uncertain in the short term. The Company will continue to monitor relevant policy developments, communicate with local healthcare authorities, and seek to expand medical insurance coverage of its products in additional provinces and municipalities as the regulatory framework becomes more standardised.

- *Convenience and cost effectiveness.* IHepcomf (艾馨甘) offers a non-invasive alternative that may reduce the need for unnecessary invasive procedures, which helps lower overall healthcare costs. In addition, patients do not need to fast or discontinue common medications (e.g., antihypertensive, antidiabetic, or hepatoprotective drugs) prior to testing.
- *Comprehensive coverage of liver cancer subtypes.* IHepcomf (艾馨甘) covers a wide spectrum of pathological subtypes of liver cancer, including hepatocellular carcinoma (“HCC”), intrahepatic cholangiocarcinoma (“ICC”), combined HCC-ICC, and other rare subtypes. It demonstrates high detection performance across these categories, with sensitivity consistently above 90.00%.
- *Complementing imaging-based diagnosis.* In clinical practice, some patients present with atypical liver lesions that cannot be clearly diagnosed as benign or malignant by imaging. For these cases, IHepcomf (艾馨甘) achieves a sensitivity of 88.00% and a specificity of 89.13%, effectively addressing the limitations of imaging and supporting physicians in making informed decisions, while reducing the need for unnecessary biopsies.
- *Upgraded sample processing workflow.* Through continuous process optimization, we have integrated plasma cfDNA extraction and methylation conversion into a single-step reagent kit. This reduces cfDNA loss during processing, enhances detection sensitivity, and simplifies the workflow. The total turnaround time for IHepcomf (艾馨甘) test per sample is approximately four and a half hours.

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Market Opportunity and Competition

The field of liver cancer gene methylation testing is currently at a critical stage of technological breakthrough and market expansion. Incidence of liver cancer in the PRC increased from 343.4 thousand in 2019 to 382.8 thousand in 2024 and is projected to reach 443.8 thousand by 2033.

China liver cancer early detection market size grew rapidly from RMB89.4 million in 2019 to RMB196.6 million in 2024, with a CAGR of 17.1% for the period from 2019 to 2024. The market is projected to grow at a CAGR of 36.6% from 2024 to 2033, with the market size projected to reach RMB3,248.7 million by 2033. As of the Latest Practicable Date, there were four early liver cancer detection products based on different technology platforms approved for marketing in China.

In addition, China’s liver cancer recurrence prediction and monitoring market has grown rapidly, expanding from RMB21.2 million in 2019 to RMB45.0 million in 2024 at a CAGR of 16.3%. The market is projected to reach RMB454.3 million by 2033, representing a CAGR of 29.3% from 2024 to 2033. The growth is driven by rising liver cancer incidence, high recurrence rates post-treatment, increasing adoption of molecular MRD technologies, and greater clinical recognition of the value of early recurrence detection in improving patient survival.

For details on the market opportunities and competitive landscape for IHepcomf (艾馨甘), see “Industry Overview – Liver Cancer Early Detection and Recurrence Monitoring Market” in this document.

Summary of Clinical Trial for Liver Cancer Early Detection

We have completed a largescale multi-center registrational trial in China to evaluate the performance of IHepcomf (艾馨甘). We acted as the sponsor for the clinical trial, which was completed in three centers, with Zhongnan Hospital of Wuhan University (武漢大學中南醫院) as the principal clinical trial institution. The clinical trial results demonstrate that IHepcomf (艾馨甘) exhibits strong clinical sensitivity and specificity, meeting the requirements for clinical application.

Clinical trial design

A blinded, comparative study was designed to evaluate the clinical performance of the GNB4 and Riplet Gene combination in IHepcomf (艾馨甘) against the clinical reference standards, which was defined as a comprehensive diagnosis made by physicians based on clinical guidelines and standard diagnostic procedures. A comparison between the clinical reference standards such as pathological examination results or imaging findings and the test results of the reagent was conducted to determine the sensitivity and specificity of the reagent, thereby verifying the clinical value of the product in identifying and detecting liver cancer. Additionally, a subset of subjects underwent blinded comparison between IHepcomf (艾馨甘) and Sanger sequencing to assess the analytical accuracy of IHepcomf (艾馨甘). The accuracy assessment of IHepcomf was conducted to evaluate the consistency between the test results and the true values of the methylation status of the target gene sequences. Accordingly, Sanger sequencing was selected as the comparative reference method.

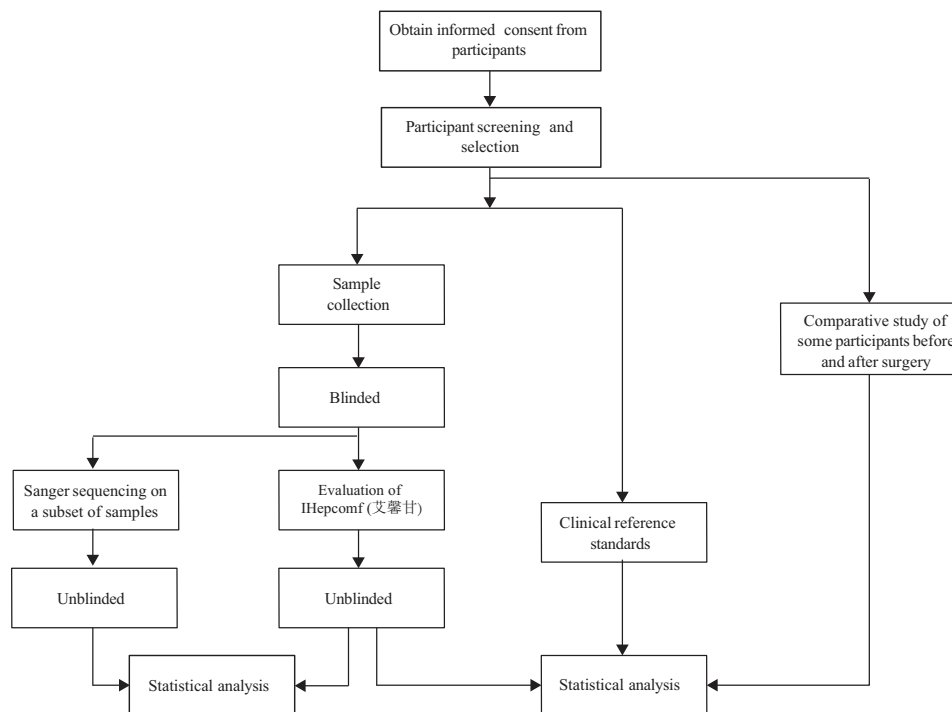
A total of 1,248 participants were enrolled in the trial among whom 1,182 are evaluable. Eligible participants include suspected liver cancer patients and interfering patients. Suspected liver cancer patients clinical diagnostic backgrounds included hepatocellular carcinoma, intrahepatic cholangiocarcinoma, mixed hepatocellular carcinoma, and other malignant liver neoplasms. Interfering patients clinical diagnostic backgrounds included benign liver tumors, benign liver diseases, and other digestive and non-digestive-system malignancies excluding liver cancer. All participants were between the age of 14 and 91, with approximately 36.4%

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participants are eventually classified as liver cancer cases (430/1182), while the remaining participants were classified as non-liver cancer cases (752/1182).

Clinical trial procedure

Set forth below is a summary of the clinical trial procedures for IHepcomf (艾馨甘):



Clinical trial results

To evaluate the performance of a clinical test, sensitivity and specificity are often used: sensitivity refers to the likelihood of a clinical test to correctly identify the individuals who truly have the disease, and a high sensitivity reduces the instances of false negative (i.e. individuals with the disease are tested negative by the test); whereas specificity refers to the likelihood of a clinical test to correctly identify the individuals who do not have the disease, and a high specificity reduces the instances of false positive (i.e. individuals without the disease are tested positive by the test).

IHepcomf (艾馨甘) demonstrated an overall sensitivity of 92.33% for liver cancer, and more specifically, it achieved a sensitivity of 84.43%, 93.58%, 98.13%, 100.00%, and 87.18% for Stage I, Stage II, Stage III, Stage IV, and unknown stage liver cancer, respectively. For non-liver cancer samples, IHepcomf (艾馨甘) demonstrated an overall specificity of 93.35%, including 97.57% for benign liver disease samples, 85.27% for other malignant tumor samples, and 75.86% for samples of other malignant tumors with liver metastasis. Notably, IHepcomf (艾馨甘) demonstrated a sensitivity of 84.43% for Stage I liver cancer, significantly outperforming traditional AFP (alpha-fetoprotein) testing. If detected at early stages (i.e. Stage I and Stage II), liver cancer is more likely to be cured. IHepcomf (艾馨甘) therefore provides a non-invasive tool for early detection and potential cure for liver cancer, offering significant clinical utility and social value.

The accuracy assessment showed that among the 329 samples included in the statistical analysis, the negative agreement rate, positive agreement rate, and overall agreement rate between the IHepcomf test results and Sanger sequencing results for the GNB4 gene were all

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100%. For the Riptet gene, the negative agreement rate, positive agreement rate, and overall agreement rate were 99.52%, 100%, and 99.70%, respectively.

Clinical Trial for Liver Cancer Recurrence Monitoring

The clinical trial for liver cancer recurrence monitoring began preparatory work in August 2025, including the identification of potential clinical institutions, investigators, and SMO partners; consultation with the NMPA on study design; and the completion of ethical approvals and documentation for trial initiation. In the second half of 2025, we had protocol discussion with hospitals, obtained the lead hospital’s ethics approval, and completed trial filing with the Hubei Provincial Medical Products Administration. We already started the process of participant enrollment.

Commercialization

We obtained the NMPA approval for Class III medical device registration for IHepcomf (艾馨甘) in January 2025 and subsequently launched IHepcomf (艾馨甘) in China. The commercialization of IHepcomf (艾馨甘) had accelerated during the Track Record Period. We achieved revenue of RMB4.5 million for the sales of IHepcomf (艾馨甘) in the year ended December 31, 2025. For details, please refer to “Financial Information – Revenue”.

Future Development Plans

In addition to the early detection of liver cancer, IHepcomf (艾馨甘) is also at the stage of clinical development for additional indications. In particular, we are conducting the clinical trials in connection with IHepcomf (艾馨甘) in cancer recurrence monitoring in China.

Regulatory framework for expansion of use

According to the Requirements and Explanations for Submission of Change Filing/Change Registration Application Materials for In Vitro Diagnostic Reagents (體外診斷試劑變更備案/變更註冊申報資料要求及說明) issued by the NMPA in 2021, changes in applicable sample types, intended population, clinical indications, or other modifications that may significantly affect a product’s clinical performance generally require submission of clinical evaluation data. The expansion of IHepcomf’s intended use to include MRD detection falls within the categories of changes in intended population and clinical indications and therefore requires a new clinical trial and registration modification. We have consulted with the NMPA and NMPA has provided a written confirmation that clinical trials are required under the regulatory framework.

The clinical trial for liver cancer recurrence monitoring began preparatory work in August 2025, including the identification of potential clinical institutions, investigators, and SMO partners; consultation with the NMPA on study design; and the completion of ethical approvals and documentation for trial initiation. In the second half of 2025, we had protocol discussion with hospitals and obtained the lead hospital’s ethics approval. We already started the process of participant enrollment and aim to submit registration application by the end of 2027.

Clinical Trial Protocol

While the clinical trial of IHepcomf for liver cancer recurrence monitoring adopts the same set of biomarkers as used in its early detection clinical trial, their trial designs are different. The clinical trial of IHepcomf for liver cancer recurrence monitoring does not require accuracy verification through Sanger sequencing, nor the inclusion of interference cases from non-liver cancer patients.

The enrolled subjects differ from those in the initial registration clinical trial. Instead of suspected liver cancer patients, the study is expected to recruit no fewer than 500 patients previously treated for primary HCC and are scheduled to undergo hepatectomy, liver transplantation, ablation therapy, or transarterial chemoembolization (TACE) for liver cancer.

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The clinical trial of IHepcomf (艾馨甘) for MRD detection will be conducted at three Class III Grade A hospitals. The patients will be regularly followed up from six to 24 months, with the collection of pre-operative and post-operative follow-up samples until either liver cancer recurrence is clinically confirmed or the trial concludes. The study will then compare IHepcomf’s test results against clinical reference standards, and calculate the sensitivity in detecting recurrent liver cancer, specificity in identifying non-recurrent cases and overall concordance rate. The aforesaid clinical trial protocol is generally in-line with the industry norm.

The primary endpoints are to assess the sensitivity of IHepcomf in detecting recurrent HCC and specificity in non-recurrent patients. No secondary endpoints are currently defined in the study protocol.

Although we did not encounter significant issues enrolling participants for IHepcomf so far, we may counter challenges going forward. See “Risk Factors – If we encounter difficulties enrolling and retaining participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.”

CE certificate

We have also been consistently exploring opportunities for IHepcomf in the EU market. To facilitate market entry and test market for IHepcomf, we obtained a CE certificate for IHepcomf in 2022.

IHepcomf was categorized under the “Other” classification under the then applicable regulatory framework, with its certification pathway involving the manufacturer’s Declaration of Conformity, preparation of technical documentation, and submission of basic product information to the relevant EU medical device authority and were not required to provide clinical data from the EU at the time it applied for registration. Obtaining CE certificate provided a foundational regulatory milestone for our future commercialization efforts in the EU market. Our priority, however, is on obtaining NMPA registration certificate and commercialise IHepcomf in the PRC considering its proximity and familiarity with the PRC market. As such, we have not made large scale promotional efforts of our products in the EU market since obtaining CE certificate.

Following recent regulatory updates in the EU market, according to the IVDR classification rules, devices used for screening, diagnosis, or staging of cancer are reclassified as Class C. As such, IHepcomf falls under this category. Under the IVDR classification rules, Class C products must undergo mandatory conformity assessment by a notified body, and performance evaluation must be supported by scientifically valid analytical and clinical data. We have discussed these new classification requirements with our notified body, and, consistent with our other IVD products certified under the previous framework, IHepcomf will be required to meet the new IVDR Class C standards and has to provide clinical trial data from the European population to supplement its existing CE certification, as data from the Chinese population alone may not satisfy IVDR requirements. We will carry out necessary actions to fulfil the updated regulatory requirements in due course.

We are in the process of executing our sales and marketing plans for IHepcomf (艾馨甘) considering its NMPA approval obtained in January 2025 and in anticipation of the NMPA approval for the MRD detection of IHepcomf (艾馨甘) within the next few years. We intend to build our commercialization capabilities through a combination of efficient and specialized internal sales and marketing teams and external marketing and distribution partnerships, with the goal of achieving broad product access globally. Please refer to “– Sales and Marketing” in this section and “Future Plans and [REDACTED] – [REDACTED]” in this document.

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WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET IHEPCOMF (艾馨甘) WITH NEW INDICATIONS SUCCESSFULLY.

IUrisure (艾光樂) – Our Core Product

IUrisure (艾光樂) is an internally developed, non-invasive urine-based test designed for the early detection of urothelial cancer. It pioneers the use of novel methylation biomarkers to accurately identify urothelial cancer, offering both diagnostic and surveillance capabilities. Leveraging our proprietary DMLT and an optimized detection methodology, IUrisure (艾光樂) achieves high sensitivity by using only 1 mL of urine sample, significantly outperforming industry standards in sample efficiency, reducing patient burden and logistics complexity. We obtained the NMPA approval for Class III medical device registration for IUrisure (艾光樂) in October 2025.

Testing Process

- *Physician consultation & initial risk assessment.* When a patient presents with symptoms or risk factors for bladder cancer (which represents approximately 90% to 95% of urothelial cases), the physician will assess their medical history and clinical background to determine whether the patient is suitable for the IUrisure (艾光樂) urothelial cancer detection test.
- *Urine sample collection.* If the patient agrees to proceed with testing, they will collect 20-30 mL of fresh midstream urine (which must be the first or second urination after waking up). The sample is poured into a preservation bottle containing urine preservation solution. The bottle cap is securely tightened and inverted at least 3 times to mix thoroughly, avoiding liquid splashing.
- *DNA extraction & PCR amplification.* DNA is extracted from urine sample using dedicated nucleic acid extraction and purification reagents. The extracted DNA undergoes bisulfite conversion, which enables the differentiation of methylated from unmethylated sequences during PCR amplification. The bisulfite-converted DNA is added to a PCR reaction mix containing specific primers and fluorescent probes targeting the methylated regions of the AL021918.2 gene and VIM gene, as well as the internal control gene ACTB. The reaction is run on a compatible real-time PCR instrument. Fluorescence signals are collected, and amplification curves are analyzed to determine the presence of methylation in the target genes.
- *Risk report & follow-up.* PCR data is interpreted using defined cycle threshold (“Ct”) value thresholds and amplification curve profiles. A positive result (methylation detected in either or both AL021918.2 gene and VIM gene) suggests a higher risk of bladder cancer, and further clinical evaluations such as endoscopy may be recommended. A negative result (no methylation detected in either gene) suggests a lower risk, though regular monitoring may still be warranted depending on the patient’s overall clinical background.

Product Development and Design

Sets forth below is a detailed timeline of the R&D progress for IUrisure (艾光樂):

- July 2021: started research and development of IUrisure (艾光樂).
- June 2023: obtained ethics approval from the lead clinical trial site.
- October 2023: completed the filing for registrational trial of IUrisure (艾光樂) with Hubei MPA.

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- November 2023: commencement of clinical trial for IUrisure (艾光樂), with a total of 1,676 participants enrolled for the clinical efficacy study as of June 2025.
- June 2024: completed the first registrational trial of IUrisure (艾光樂).
- July 2024: submitted formal application to NMPA for IUrisure (艾光樂) to be registered as a Class III medical device.
- September 2024: received supplementary notice from the NMPA.
- January 2025: IUrisure (艾光樂) completed the preparatory work for the supplemental clinical trial and began enrolling samples.
- June 2025: IUrisure (艾光樂) completed sample collection with a total of 530 samples enrolled.
- July 2025: completed supplemental clinical trial for IUrisure (艾光樂)⁽¹⁾.
- September 2025: submitted supplementary clinical trial documentation to the NMPA.
- October 2025: IUrisure (艾光樂) obtained registration certification from NMPA.
- October 2025: commenced preparatory work for the clinical trial for recurrence monitoring in urothelial carcinoma.
- December 2025: IUrisure (艾光樂) commenced preparatory work for EU IVDR certification.
- We plan to sign a collaboration agreement with the lead hospital and complete the trial filing with the Hubei MPA in April 2026.

Notes:

- (1) The supplemental clinical study of the IUrisure was conducted to further evaluate its clinical performance and analytical accuracy in accordance with NMPA registration review requirements. The trial maintained the same objectives and design as the initial registration study, with an expanded sample size including additional urothelial carcinoma and interference samples as requested by the regulator. The results are as follow:

Parameter	Initial Clinical Sample Size (N)	Supplemental Clinical Sample Size (N)	Total (N)
Subjects screened	1,180	545	1,725
Cases excluded	37	3	40
Pilot test samples	9	0	9
Subjects enrolled	1,134	542	1,676
Cases removed from analysis	93	12	105
Included in statistical analysis	1,041	530	1,571

In total, 1,725 subjects were screened, with 1,676 enrolled and 1,571 valid cases included in statistical analysis (comprising 530 newly added samples). Among these, the IUrisure assay completed testing on 530 samples, including 339 UC cases and 191 non-UC cases. Results showed a sensitivity of 93.51% and specificity of 93.72%, consistent with previous clinical findings and reaffirming the assay’s reliability and clinical effectiveness for non-invasive UC diagnosis.

Development Process

Using methylation data from 440 UC tissues and 21 adjacent normal tissues in the TCGA database, iTBFinder identified Differentially Methylated Region (“DMRs”) with prominent cancer-specific signals. The specificity of these DMRs was further evaluated using methylation data from healthy human blood cells and other cancer and adjacent normal tissues within the TCGA and GEO databases, resulting in eight candidates of DMRs with favourable specificity.

Based on the verification using Sanger Sequencing of 30 healthy blood leukocyte and 20 normal tissue samples produced five candidates of DMGs. Testing in UC tissues further narrowed the selection to four candidates, which were subsequently evaluated in 477 clinical

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urine samples (comprising 264 UC cases and 213 healthy controls, divided into training and validation cohorts).

The dual-marker combination of VIM and AL021918.2 demonstrated the strongest diagnostic performance, with an AUC of 0.96, leading to the final identification of the dual-biomarker combination VIM and AL021918.2. Multiple studies have also confirmed that the methylation of the target genes VIM and AL021918.2 in IUrisure shows performance in the detection of urothelial carcinoma.

Technology

Our IUrisure (艾光樂) urothelial cancer test employs a similar testing methodology to that of IHepcomf (艾馨甘) by targeting DNA methylation patterns in urine samples. This test detects methylation changes in specific CpG regions of AL021918.2 gene and VIM gene, which are closely associated with urothelial cancer development. In urothelial cancer samples, the methylation level of AL021918.2 gene shows significant differences compared with control samples, making it a suitable marker for diagnosing urothelial cancer. VIM gene encodes a type III intermediate filament protein involved in cell differentiation and promoting tumor cell invasiveness. It is closely related to malignancy, invasion, metastasis, and poor prognosis. Multiple studies have confirmed that methylation of VIM gene is highly correlated with the occurrence of urothelial cancer. AL021918.2 gene and VIM gene are thus highly promising methylation-based urine detection markers for urothelial cancer.

The IUrisure (艾光樂) testing process begins with the collection of urine samples using our special collection devices, which contain preservation solution to prevent nucleic acid degradation. DNA is extracted from exfoliated cells in urine using magnetic bead-based nucleic acid purification, along with cfDNA. The purified DNA undergoes bisulfite conversion, which converts unmethylated cytosines to uracils while methylated cytosines remain unchanged, creating sequence differences that distinguish between methylated and unmethylated DNA. We utilize methylation-specific primers and fluorescent probes targeting the bisulfite-converted sequences of AL021918.2 gene and VIM gene. Real-time PCR amplification is performed, with methylation detection signals captured through the FAM channel for VIM gene and the ROX channel for AL021918.2 gene. An internal control gene, ACTB (β -Actin), is simultaneously amplified through the VIC channel to assess DNA quality and quantity. Similar to our other tests, each IUrisure (艾光樂) test includes both positive and negative controls to ensure reliability and consistency. The system analyzes the amplification curves and Ct values to determine the presence or absence of methylation in the target genes, and results are interpreted according to predefined thresholds to generate a risk assessment report for clinical decision-making.

Competitive Advantages

IUrisure (艾光樂) has the following advantages:

- *Advanced and proprietary technology and know-how.* Similar to IHepcomf (艾馨甘), IUrisure (艾光樂) leverages DMLT and identifies an optimal panel of biomarkers specifically suited for urine-based detection of urothelial cancer.
- *High sensitivity.* IUrisure (艾光樂) utilizes an optimized urine-based testing technology, which allows high sensitivity by using only 1 mL of urine sample, significantly outperforming industry standards in sample efficiency, reducing patient burden and logistics complexity.
- *Novel methylation biomarkers.* IUrisure (艾光樂) pioneers the use of novel methylation biomarkers to accurately identify urothelial cancer, offering diagnostic capabilities.

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- *Clinical performance.* Validated in 1,571 clinical samples, IUrisure (艾光樂) demonstrated excellent performance with a sensitivity of 92.94% and a specificity of 92.83%. The test shows sensitivity above 90.00% across multiple urothelial cancer subtypes, including bladder cancer, renal pelvis cancer, ureteral cancer, and multifocal urothelial carcinoma.
- *Early detection.* IUrisure (艾光樂) effectively detects early-stage urothelial cancer, achieving 85.45% sensitivity for Ta-stage and 93.43% sensitivity for Stage I urothelial cancer.
- *Convenience.* IUrisure (艾光樂) is a non-invasive, urine-based test which is easy for end users. It allows our users to collect samples by themselves or in a hospital setting, directly at the clinic. The sampling process generally takes less than five minutes.

Market Opportunity and Competition

IUrisure’s primary target market is China and the EU which has high and rising incidence of UC, reflecting strong clinical demand and expanding market potential. IUrisure detects methylation of UC-related genes in urine samples, offering a non-invasive, convenient, and highly accurate alternative to traditional diagnostic methods.

According to Frost & Sullivan, urothelial cancer encompasses bladder cancer, ureter cancer, and renal pelvis cancer, with bladder cancer accounting for 90 to 95 % of urothelial cases. Bladder cancer is one of the most common urological malignancies in China, with incidence steadily increasing. New cases rose from 84.8 thousand in 2019 to 98.8 thousand in 2024. The number is projected to reach 123.4 thousand by 2033. On a global scale, out of 204 countries and territories, China is at the top of the list for the most deaths due to bladder cancer, according to Frost & Sullivan.

Bladder cancer risk is high in China due to widespread smoking and occupational exposure to carcinogens like aromatic amines. China’s national Diagnosis and Treatment Guideline for Bladder Cancer (2022 Edition) (《膀胱癌診療指南(2022年版)》) characterizes bladder cancer as peaking in the population aged between 50 and 70, which are considered as the recommended populations for urothelial cancer detection, according to Frost & Sullivan. Total recommended populations for early detection of urothelial cancer increased from 349.7 million to 390.0 million from 2019 to 2024, and is expected to further increase to 408.5 million in 2033. Despite the mass population recommended for urothelial cancer early detection, the penetration rate among such population is low in China, with 0.5% in 2024.

China’s bladder cancer early detection market has expanded rapidly since 2022, reaching RMB98.0 million in 2024. The market is projected to grow at a CAGR of 14.0% from 2024 to 2033, reaching RMB319.6 million by 2033. This growth is driven by rising disease awareness, increasing adoption of non-invasive molecular diagnostics, and broader detection initiatives targeting high-risk populations. Currently there are several bladder cancer tests approved in China applying qPCR technology targeting various gene methylations. IUrisure (艾光樂) pioneers the use of novel methylation biomarkers AL021918.2 gene and VIM gene, enabling high sensitivity and specificity. For details on the market opportunities and competitive landscape for IUrisure (艾光樂), see “Industry Overview – Urothelial Carcinoma (UC) Early Detection Market” in this document.

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Summary of Clinical Trial

We have completed a large-scale multi-center registrational trial in China to evaluate the performance of IUriure (艾光樂). We acted as the sponsor for the clinical trial, which was completed in three centers, with Peking University First Hospital (北京大學第一醫院) as the principal clinical trial institution. The clinical trial results demonstrate that IUriure (艾光樂) exhibits strong clinical sensitivity and specificity, meeting the requirements for clinical application.

A blinded, comparative study was designed to evaluate the clinical performance of IUriure (艾光樂) against the clinical reference standards, which was defined as a comprehensive diagnosis made by physicians based on clinical guidelines and standard diagnostic procedures. For urothelial carcinomas and benign urothelial tumors, standard diagnostic procedure diagnosis served as the reference; for other disease groups, comprehensive diagnosis followed standard imaging and clinical guidelines (including but not limited to abdominal or pelvic ultrasound, urinary CT, CTU, or retrograde urography). The comparison between the clinical reference standards such as pathological examination results or imaging findings and the test results of the reagent was used to determine the sensitivity and specificity of the reagent, thereby validating the clinical value of the product in identifying and detecting urothelial carcinoma. Additionally, a subset of subjects underwent blinded comparison between IUriure (艾光樂) and Sanger sequencing to assess the analytical accuracy of IUriure (艾光樂). The accuracy assessment was conducted to evaluate the consistency between the test results and the true values of the methylation status of the target gene sequences.

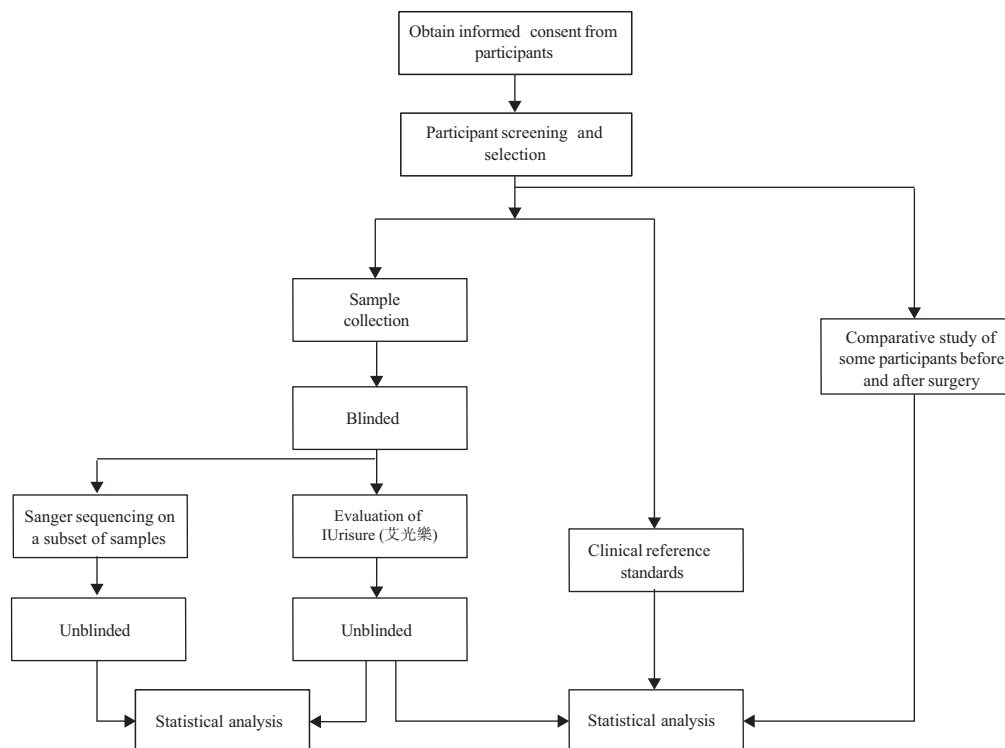
A total of 1,676 participants were enrolled in the trial among whom 1,571 are evaluable. Eligible participants included those presenting with clinical symptoms (e.g., hematuria, bladder irritation, flank pain), abnormal findings on noninvasive imaging requiring further evaluation, newly diagnosed patients in whom cystoscopy could not be determined by imaging, as well as patients with benign urological diseases or other confirmed or suspected malignancies. All participants were between the age of 18 and 96, with approximately 40.5% participants are eventually classified as urothelial cancer cases (637/1,571), while the remaining participants were classified as non-urothelial cancer cases (934/1,571). Although we did not encounter significant issues enrolling participants for IUriure so far, we may counter challenges going forward. See “Risk Factors – If we encounter difficulties enrolling and retaining participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.”

For the pre- and post-surgery comparison study, 33 participants were enrolled, with 31 participants valuable for analysis. Among them, 28 participants were positive preoperatively and negative postoperatively; two participants remained positive both pre- and postoperatively; and one participant remained negative both pre- and postoperatively. These results indicate that target gene methylation levels in urine decreased after surgical removal of urothelial cancer.

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Clinical trial procedure

Set forth below is a summary of the clinical trial procedures for IUriSure (艾光樂):



Clinical trial results

To evaluate the performance of a clinical test, sensitivity and specificity are often used: sensitivity refers to the likelihood of a clinical test to correctly identify the individuals who truly have the disease, and a high sensitivity reduces the instances of false negative (i.e. individuals with the disease are tested negative by the test); whereas specificity refers to the likelihood of a clinical test to correctly identify the individuals who do not have the disease, and a high specificity reduces the instances of false positive (i.e. individuals without the disease are tested positive by the test).

IUriSure (艾光樂) demonstrated an overall sensitivity of 92.94% for urothelial cancer, and more specifically, it achieved a sensitivity of 85.45%, 97.06%, 93.43%, 96.05%, 100.00%, 100.00% and 93.88% for Ta-Stage, Tis Stage, Stage I, Stage II, Stage III, Stage IV, and unknown stage urothelial cancer, respectively. For non-urothelial cancer samples, IUriSure demonstrated an overall specificity of 92.83%, including 93.57% for benign urinary system disease samples, 82.96% for other malignant tumors of the urinary system, and 97.74% for non-urinary system malignant tumors. IUriSure (艾光樂) achieved 85.45% sensitivity for Ta-stage and 93.43% sensitivity for Stage I urothelial cancer, enabling accurate detection of urothelial cancer in early stages.

A total of 315 participants were enrolled for analytical accuracy assessment, with 293 participants valuable for analysis. For the VIM gene, the positive concordance rate was 99.21%, the negative concordance rate was 98.80%, and the overall concordance rate was 98.98%. For the AL021918.2 gene, the positive concordance rate was 98.43%, the negative concordance rate was 100.00%, and the overall concordance rate was 99.32%.

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The abovementioned results indicate that IUrisure (艾光樂) demonstrates high sensitivity and specificity for the clinical diagnosis of urothelial cancer, and its methylation detection shows excellent concordance with Sanger sequencing, supporting its clinical utility.

Future Development Plans

In addition to the early detection of urothelial cancer, IUrisure (艾光樂) is also at the stage of clinical development for additional indications. In particular, we are preparing for the clinical trials in connection with IUrisure (艾光樂) in cancer recurrence monitoring.

We have commenced preparatory work for the clinical trial for recurrence monitoring in urothelial carcinoma in October 2025, including the identification of potential clinical institutions and investigators, and the completion of ethical reviews and documentation related to the clinical protocol and trial initiation. Approval from ethics committee of the lead hospital is expected to be received in April 2026. Subsequently, we plan to sign a collaboration agreement with the lead hospital and complete the trial filing with the Hubei MPA. The first stage of the clinical trial, covering patient enrollment and follow up, is expected to continue until 2028 with NMPA registration approval targeted in 2029.

This clinical trial focuses on monitoring recurrence in patients who have undergone surgical treatment for urothelial carcinoma. We have engaged in discussions with a hospital in Beijing which will serve as the lead institution, and the trial is planned to be conducted at three participating hospitals. A total of no fewer than 500 patients scheduled to undergo surgical treatment for urothelial carcinoma will be recruited and followed over time, with sample collection conducted before and after surgery until recurrence is clinically confirmed or the study concludes. The primary endpoints are to evaluate the sensitivity of IUrisure in detecting recurrent urothelial carcinoma and the specificity in patients without recurrence, while no secondary endpoints are included in the current protocol.

We have also been consistently exploring opportunities for IUrisure in the EU market. To facilitate market entry, we are in the process of obtaining a CE certificate for IUrisure. Under the requirements of the In Vitro Diagnostic Regulation (“IVDR”), we must first establish a quality management system in compliance with ISO 13485 standards, conduct a clinical evaluation, and submit sufficient clinical data to demonstrate the product’s safety and effectiveness, with validation based on the Chinese population already completed. We are currently preparing the technical documentation and have preliminarily selected a notified body recognized by the European Union to conduct the conformity assessment. Upon successful review, the product will obtain CE certification, following which we will conduct post-market surveillance, report adverse events as required, and update the technical documentation on an ongoing basis.

According to the IVDR classification rules, devices used for screening, diagnosis, or staging of cancer are classified as Class C. As such, IUrisure falls under this category. Under the IVDR classification rules, Class C products must undergo mandatory conformity assessment by a notified body, and performance evaluation must be supported by scientifically valid analytical and clinical data. Based on communications with the notified body, it is required that the product be supported by clinical trial data from the European population to demonstrate its scientific validity, as data from the Chinese population alone may not satisfy IVDR requirements. Accordingly, we are expected to supplement clinical data from European populations for CE certification application of IUrisure.

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WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET IURISURE (艾光樂) WITH NEW INDICATIONS SUCCESSFULLY.

Our Other Products and Product Candidates

Pipeline products

We have a well-positioned pipeline of single- and multi-cancer early detection tests in early to advanced stage of development. Other pipeline products include (i) single-cancer early detection tests *IStomacomf* (艾衛元), *IPulmocomf* (艾斐暢), and *IUterasure* (艾宮樂) and (ii) multiple cancer detection test *PanCa-6* (艾露元).

***IStomacomf* (艾衛元)**

IStomacomf (艾衛元) is a blood-based gastric cancer detection test currently under development. It targets the methylation status of two gastric cancer-associated genes. Biomarker selection for *IStomacomf* (艾衛元) was guided by our proprietary DMLT, while the assay is optimized with our proprietary cfDNA extraction and conversion kits for sensitive detection of ctDNA. We have successfully completed prototype kit development, small-scale performance testing, and pilot production for *IStomacomf* (艾衛元).

***IPulmocomf* (艾斐暢)**

IPulmocomf (艾斐暢) is a blood-based lung cancer detection test that analyzes methylation of three lung cancer-associated genes. Designed as a diagnostic aid for patients with suspicious lung lesions identified through imaging or other clinical assessments, the test combines DMLT technology with optimized cfDNA extraction and conversion chemistry. We have completed prototype kit technology and small-scale performance evaluation for *IPulmocomf* (艾斐暢).

***IUterasure* (艾宮樂)**

IUterasure (艾宮樂) is an endometrial cancer test that detects the methylation status of two endometrial-cancer-related genes in cervical exfoliated cells using qPCR technology. The test builds on Johns Hopkins Kimmel Cancer Center findings that cervical cell samples contain shed endometrial cells, enabling endometrial cancer detection with far less trauma than hysteroscopic biopsy or diagnostic curettage. We have completed prototype kit development and small-scale performance testing for *IUterasure* (艾宮樂). *IUterasure* (艾宮樂) received CE-IVD CE Mark in May 2022.

***PanCa-6* (艾露元)**

PanCa-6 (艾露元) is a blood-based multi-cancer early detection test for six high-incidence cancers, including lung, colorectal, gastric, liver, esophageal and pancreatic cancers. *PanCa-6* (艾露元) assay analyzes cfDNA methylation of six tumor-associated genes using qPCR. Built on our proprietary DMLT technology, *PanCa-6* (艾露元) incorporates the MLP Cancer Classifier to map detected methylation patterns to organ-specific cancer risks. We have reached the stage of prototype kit development, algorithm validation, and preliminary performance testing for *PanCa-6* (艾露元).

Commercialized products

In addition to *IHepcomf* (艾馨甘) and *IUrisure* (艾光樂), our other commercialized products include *IColocomf* (艾長康), *IColohunter* (艾長健), *IESohunter* (艾思寧) and *ICervsure* (艾宮舒).

***IColocomf* (艾長康)**

IColocomf (艾長康) is a non-invasive stool-based test for early colorectal cancer detection. We obtained the NMPA approval for Class III medical device registration for *IColocomf* (艾長

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康) in March 2022 and the CE-IVD Mark in June 2021. During the Track Record Period, IColocomf (艾長康) has been our flagship product, whose sales accounted for the majority of our revenue. For the revenue generated from our sales of IColocomf (艾長康), please refer to “Financial Information – Revenue” in this document.

IColocomf (艾長康) uses qPCR to detect methylation of two colorectal cancer-related genes in intestinal cells shed in stool. Proprietary dual-target and signal enrichment technologies allow the test to detect methylated DNA at levels as low as 1% from just 2 mL of stool suspension. Sample processing in a test with IColocomf (艾長康) is fully automatable, and results can be obtained in approximately four and a half hours, significantly faster than comparable products. For the patent protection over IColocomf (艾長康), please refer to “Appendix V – Statutory and General Information – B. Further Information about Our Business – 2. Intellectual Property Rights.” in this document. For the competitive landscape of IColocomf (艾長康), please refer to “Industry Overview – Colorectal Cancer (CRC) Early Detection Market” in this document.

IColohunter (艾長健)

IColohunter (艾長健) is a blood-based colorectal cancer test that detects methylation of two colorectal cancer-related genes in plasma using qPCR technology. We have identified the blood-based biomarkers NTMT1 and MAP3K14-AS1 for colorectal cancer through our proprietary iTBFinder platform and adopted them in IColohunter (艾長健). We obtained the NMPA approval for Class III medical device registration for IColohunter (艾長健) in September 2024 and CE-IVD Mark in March 2022. For the revenue generated from our sales of IColocomf (艾長健), please refer to “Financial Information – Revenue” in this document.

Leveraging proprietary marker selection algorithms and cfDNA extraction technology, IColohunter (艾長健) identifies minimum amounts of ctDNA with high accuracy. Clinically, IColohunter (艾長健) achieves 91.42% sensitivity for colorectal cancer, 44.16% sensitivity for advanced adenomas, 73.53% for high-grade intraepithelial neoplasia, and 91.74% specificity, making it the only NMPA-approved blood-based colorectal cancer test with both sensitivity and specificity exceeding 90%. For the patent protection over IColohunter (艾長健), please refer to “Appendix V – Statutory and General Information – B. Further Information about Our Business – 2. Intellectual Property Rights.” in this document. For the competitive landscape of IColohunter (艾長健), please refer to “Industry Overview – Colorectal Cancer (CRC) Early Detection Market” in this document.

IEsohunter (艾思寧)

IEsohunter (艾思寧) is a blood-based test for esophageal cancer, targeting patients with suspected disease who are medically unfit for endoscopy procedures or unwilling to undergo such procedures. We have identified the blood-based biomarkers KCNA3 and OTOP2 for oesophageal cancer through our proprietary iTBFinder platform and adopted them in IEsohunter (艾思寧). We obtained the NMPA approval for Class III medical device registration for IEsohunter (艾思寧) in January 2025 and CE-IVD Mark in March 2022. The commercialization of IEsohunter (艾思寧) has accelerated during the Track Record Period. For the revenue generated from our sales of IEsohunter (艾思寧), please refer to “Financial Information - Revenue” in this document.

Our IEsohunter (艾思寧) provides a non-invasive, one-tube test for esophageal cancer, addressing the limitations of traditional endoscopy. For the patent protection over IEsohunter (艾思寧), please refer to “Appendix V – Statutory and General Information – B. Further Information about Our Business – 2. Intellectual Property Rights.” in this document. For the competitive landscape of IEsohunter (艾思寧), please refer to “Industry Overview – Esophageal Cancer Early Detection Market” in this document.

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ICervsure (艾宮舒)

ICervsure (艾宮舒) is a cervical cancer test that detects methylation of two cervical-cancer-related genes in exfoliated cervical cells using qPCR technology. ICervsure (艾宮舒) is intended for patients who test positive for HPV or present with abnormal cytology results, providing physicians with an additional tool to assess the risk of precancerous lesions or early cervical cancer and guide further diagnostic decisions. For the competitive landscape of ICervsure (艾宮舒), please refer to “Industry Overview – Cervical Cancer Early Detection Market” in this document.

We completed the pre-clinical development of ICervsure (艾宮舒) in 2017. In May 2018, we entered into a technology collaboration agreement (the “**Out-licensing Agreement**”) with HybriBio Biotech which was subsequently amended in March 2019. According to the Out-licensing Agreement, we granted HybriBio Biotech the exclusive rights to utilize the patents, patent applications and know-how to develop, manufacture and commercialize ICervsure (艾宮舒) in the PRC, for a period of 10 years after obtaining the Class III medical registration of ICervsure (艾宮舒). HybriBio Biotech subsequently completed the clinical development of ICervsure (艾宮舒) in China. For details, please refer to “Research and Development – Licensing Arrangement” in this section.

RESEARCH AND DEVELOPMENT

We focus on developing technologies to enhance our existing pipeline and to develop new cancer tests. We believe that our success has depended and will continue to depend to a large extent on our ability to develop new or improved cancer detection products. As of the Latest Practicable Date, we had a number of early cancer detection products pending clinical trials or NMPA approval. The time required from developing to commercializing a new product varies by product candidate and can be affected by various factors which may be beyond our control, such as clinical trial results and government policies and approvals. We incurred research and development costs of RMB15.0 million and RMB21.3 million in the years ended December 31, 2024 and 2025 respectively.

Technology Platforms

At the core of our innovation is our proprietary DMLT. This technology can efficiently screen for cancer-specific epigenetic alterations across the entire human genome. The DMLT integrates AI-driven algorithms to construct a standardized cancer biomarker database. Using high-throughput methylation arrays and next-generation sequencing data, DMLT scans genome-wide methylation sites from cancer samples (including tissue, blood, and stool), covering tens of thousands of cancer-associated CpG islands. Machine learning models (such as Random Forest and deep learning) are then applied to analyze methylation data, filter out noise, and identify highly cancer-specific methylation biomarker panels. Furthermore, by consolidating biomarker datasets across multiple cancer types (e.g., digestive system and gynecological cancers), DMLT establishes a standardized database containing key clinical performance indicators such as sensitivity and specificity, thereby supporting robust product development.

The DMLT, combining multiple proprietary technologies, including iTBFinder, MLP Cancer Classifier, SEM-PCR technology and AS-Cap technology, forms our technology platform. This integrated approach enables a full-chain workflow from biomarker discovery to clinical testing, allowing for the reliable identification of early-stage cancers and precancerous lesions using non-invasive samples (e.g., blood, stool).

iTBFinder Database and AI-Enhanced Biomarker Discovery

Biomarkers play a critical role in early cancer detection. Since our inception, we have focused on the discovery of key biomarkers for early cancer detection and have built a

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proprietary biomarker selection platform, the iTBFinder. Leveraging multi-omics datasets across 22 cancer types and more than 13,800 clinical samples. The iTBFinder database currently has over 210,000 multi-omics data entries, enabling precise and efficient biomarker identification and continuous pipeline expansion. We have registered two software copyrights in relation to our iTBFinder database with registration number of (i) 2021SR0042982 and (2) 2022SR1344457. For details, please refer to “– Intellectual Property” in this section and “Appendix V – Statutory and General Information – B. Further Information about Our Business – 2. Intellectual Property Rights.” in this document.

Built on multi-omics data and inspired by tumor genome evolution theory, we created a tumor genome evolution simulation algorithm that effectively addresses the scarcity of early-stage tumor samples. For biomarker discovery, we apply multiple ensemble learning models including Random Forest and XGBoost to identify potential cancer biomarker candidates. Random Forest, a multi-decision-tree machine learning algorithm, enables classification of large input variables while assessing feature importance. It is particularly robust when dealing with imbalanced classification datasets, offering error balancing and strong tolerance to outliers and noise, which allows for integrative analysis across multiple datasets. In addition, XGBoost, a distributed gradient boosting decision tree algorithm, introduces regularization and leverages second-order derivative information to enhance performance. Using XGBoost, we perform comprehensive analysis and model training across genome-wide methylation sites, achieving higher predictive accuracy compared to conventional models such as logistic regression or support vector machines.

Each candidate biomarker is further evaluated with a molecular dynamics–based scoring model to guide optimal PCR primer design and determine clinical development feasibility. All identified biomarkers are visualized within iTBFinder, allowing our R&D team to freely search, browse, and review each biomarker’s performance metrics and supporting omics evidence.

MLP Cancer Classifier

We have established the MLP Cancer Classifier, a cancer origin tracing algorithm based on multilayer perceptron (“MLP”) deep learning architecture. MLPs excel at capturing complex, nonlinear relationships among high-dimensional features such as gene expression and DNA methylation. Trained on large datasets, our MLP model can distinguish subtle differences between tumor types and patient subgroups with strong robustness. The datasets used to train our MLP Cancer Classifier were constructed using methylation chip datasets from TCGA and GEO, together with RNA Seq datasets from GEO to analyze the correlation between gene methylation and transcription levels. These datasets are sourced from publicly available databases and contain only grouped and sequence information without any personally identifiable or sensitive patient data. Both TCGA and GEO permit the use of open access data for research and commercial purposes; accordingly, the development of our MLP Cancer Classifier does not involve patient consent or regulatory approval requirements. Data collection and cleaning were conducted by our software engineers, feature selection and dataset partitioning were completed by one software engineer, and another software engineer was responsible for model design, training, and evaluation.

Our MLP model effectively handles incomplete datasets by predicting missing values and mitigates noise by averaging results across multiple training iterations. By employing repeated resampling and random recombination of training sets, our classifier consistently demonstrates reliable performance when applied to previously unseen samples.

SEM-PCR Technology

Our SEM-PCR technology addresses the challenge of detecting low abundance methylated DNA with high sensitivity. Our SEM-PCR technology leverages the unique characteristics of

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bisulfite-converted DNA, where double-stranded sequences are no longer complementary and methylation status differs between strands. By integrating multiple primer design with tandem probe technology, SEM-PCR generates multiple fluorescence signals from each amplified DNA molecule in every PCR cycle, boosting intensity of detection signals by more than tenfold, allowing identification of low-abundance methylation targets and overcoming the inefficiency of traditional PCR caused by strand methylation asynchrony and signal dilution. Our SEM-PCR Technology has been granted a patent under Patent No. CN202110007663.6 in China and the primers used in SEM-pCR are our proprietary assets. The performance of SEM-PCR has been evaluated against conventional qPCR, in which standard assays typically use a single primer pair and one probe for each marker. In comparison, SEM-PCR adopts a multi layered detection architecture, generally involving two to four primer pairs and associated probes for each marker. This design enhances detection sensitivity and enables the identification of low abundance methylation targets that may not be detectable using standard qPCR methods.

AS-Cap Technology

Our AS-Cap technology uses competitive capture probe design to avoid non-specific binding to bacterial and dietary DNA, which accounts for over 99.99% of stool samples, enabling highly specific capture of human DNA fragments and improving signal quality and detection efficiency. The performance of AS-Cap Technology has been evaluated against industry benchmarks for sample input requirements. Whereas conventional methods generally require stool suspension volumes of approximately 20 mL, AS Cap achieves comparable or improved detection performance using around 1.8 mL of sample, reflecting greater efficiency in sample utilization and processing.

As of the Latest Practicable Date, we have successfully completed the full cycle from laboratory development to regulatory approval of five of our products in China with an average R&D cycle of approximately four and a half years, which has established a high barrier to entry for future market participants. As of the Latest Practicable Date, we have built a portfolio of 162 patents and patent applications pending registration globally to protect our proprietary technologies and know-how.

R&D Team

We have a strong in-house research and development team of 40 members primarily based in Wuhan, China as of the December 31, 2025, with 65% holding a bachelor’s degree or higher.

By 2024, as the major clinical work for our Core Products had been substantially completed and the clinical trials of IColocomf, IEsohunter, IHepcomf, and IUrisure entered supplementary phases, only limited sample collection at clinical sites are required. We therefore reduced the number of laboratory technicians and clinical trial assistant. These were primarily entry-level positions with relatively low competency requirements and could be recruited relatively easily. The reduction in headcount did not adversely affect our core R&D capabilities or progress of Core Products, as demonstrated by the successful NMPA registration of three NMPA registrations in 2025. The core R&D personnel, including those involved in the development of the Core Products, remained with the Group during the Track Record Period and as of the Latest Practicable Date.

The next phase of our Core Product development will focus primarily on clinical research, with multi-center clinical trials currently in progress. To accelerate progress, several new members have recently joined the clinical affairs group of our R&D team to support regulatory compliance of the clinical trials with our partner SMO and CRO organizations.

In the second half of 2025, as we commenced a clinical study on recurrence monitoring for its liver-cancer program and prepared to initiate a recurrence-monitoring study for urothelial carcinoma, along with progress on IVDR registration, and planned clinical trials for gastric

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cancer and lung cancer in 2026, additional pre-clinical research and clinical preparation work were required to be accelerated. Accordingly, we recruited additional clinical trial assistants, laboratory technicians, and one regulatory affairs personnel to support these developments.

Our R&D team is led by our founder and Chairman, Dr. Zhang Lianglu, and our R&D president, Dr. Dong Lanlan. Dr. Dong is responsible for leading the overall R&D, overseeing and coordinating all activities of the R&D team. For details of the background of Dr. Zhang and Dr. Dong, please refer to “Directors and Senior Management.” In addition, we have assembled a group of talents with research and development and medical industry experience to carry out our research and development activities. Supporting Dr. Dong are our four R&D deputy directors. Mr. Wu Zhicheng (吳志誠), our Chief Information Officer, is responsible for the establishment and continuous enhancement of iTBfinder. He previously served as a professor at Westlake University (西湖大學). He participated in international collaborative studies on breast and thyroid cancers, developed a widely recognized multi-label algorithm, and has authored over a dozen SCI papers with more than 2,800 citations. He also holds numerous patents and has received two first prizes for Scientific and Technological Achievements and one second prize for Natural Science in Jiangxi Province. Dr. Zhou Dihan (周諦晗), our Chief Technology Officer, oversees the R&D technology exploration, with primary responsibility for evaluating and managing the technical feasibility of each project. She brought nearly a decade of experience from the CAS Wuhan Institute of Virology, where she led National Natural Science Foundation projects and published more than 20 SCI papers. Dr. Guo Hong (郭洪), who earned her doctorate from Huazhong Agricultural University (華中農業大學) and spent nine years at the CAS Wuhan Institute of Virology, specializing in virology and immunology. She led two NSFC projects, published 24 papers, and holds over 20 patents and patent applications. She is responsible for developing complementary Class I medical-device products and ensure they are well integrated with our Core Products. In addition, Dr. Zhou Jun (周俊), who managed NSFC projects and international collaborations, authoring multiple SCI papers and securing more than 30 patents. She is in charge of compliant product development, assisting in ensuring the scientific validity and completeness of the Company’s project research protocols.

The R&D Department also includes a clinical team and a registration team which are directly managed by Dr. Dong. The clinical team is primarily responsible for clinical validation by organizing and managing clinical trials to ensure product safety, efficacy, and full regulatory compliance. On the other hand, the registration team oversees all regulatory submissions, prepare and submit application materials, and coordinate communications with regulatory authorities to ensure timely and compliant approvals.

R&D Personnel responsible for our Core Products

The IHepcomf project and IUrisure project were led by Dr. Zhou Jun and Dr. Zhou Dihan who were responsible for leading the supplemental submission for approval and enhancement work of our Core Products. Both Dr. Zhou Jun and Dr. Zhou Dihan possess expertise in assessing technical feasibility and ensuring regulatory compliance, and have been deeply involved in managing progress, quality, and technical challenges in various development projects. Leveraging their experience and leadership, they effectively guided the team to complete the supplemental work and resubmit the registration applications in an efficient manner, which ultimately led to the successful approval of Class III medical device registrations for both IHepcomf and IUrisure.

We enter into legally-binding confidentiality and non-compete agreements with our key employees and employees involved in our research and development activities, pursuant to which any intellectual property conceived and developed during their employment belongs to us and they waive all relevant rights or claims to such intellectual property. During the Track Record Period and as of the Latest Practicable Date, substantially all key R&D personnel

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involved in the development of our Core Products remained employed by us. We have established phased development processes, set strict access control for iTBFinder and secured patent protection over our core biomarkers, thereby mitigating the potential disruptions or risks arising from the departure of individual project leaders.

Product Design and Pre-Clinical Development Procedure

We have established and strictly followed an internal protocol that governs the design and development of our products. The following diagram sets forth our product design and pre-clinical development procedure:

The key steps of our product design and development procedure is summarized as below:

- *Biomarker discovery.* The product R&D team initiates and determines the study design necessary to identify relevant biomarkers of a disease and conducts the study to identify a panel of such biomarkers suitable for diagnosing the disease.
- *Design and development inputs.* The product R&D team determines the required inputs and prepares Design and Development Plan, Risk Management Report and Compilation of Applicable Regulations and Standards, which list the product candidate’s function, performance, usability and safety requirements, applicable regulatory requirements and standards and other essential requirements for the design and development of the product candidate.
- *Design and development outputs.* The product R&D team prepares the product design, procurement list and risk management measures, designs production process and testing process and keeps design history in file and records.
- *Inspection of manufacturing suitability.* These procedures ensure that the design and development outputs are suitable for manufacturing before such outputs become final production specifications and that our production capability will suffice.
- *Validation of design and development.* The product R&D team ensures the product’s compliance with the prescribed application and other requirements, completes pre-clinical trial and evaluation. Specifically, prior to initiating clinical trials, the product R&D team will conduct validation studies.
- *Verification of design and development.* We will initiate clinical trials and various registration-related work streams for the manufacturing of our products.

All the procedures of our design and development activities must strictly follow our design and development control policy and procedures. Our project team strictly follows each step of our internal protocol, and closely monitors and reviews key stages along the design and development process.

We maintain close collaboration with leading external clinical trial institutions, covering multiple cancer types such as colorectal, esophageal, liver, and urothelial cancers. From time to time, we also co-author academic publications with our collaborators, further strengthening our scientific influence and industry recognition.

Licensing Arrangements

In May 2018, we entered into a technology collaboration agreement (the “**Out-licensing Agreement**”) with HybriBio Biotech which was subsequently amended in March 2019. According to the Out-licensing Agreement, we granted HybriBio Biotech the exclusive rights to utilize the patents, patent applications and the non-exclusive rights to use the know-how to develop, manufacture and commercialize ICervsure (艾宮舒), an early cancer detection product for cervical cancer, in the PRC (excluding Taiwan, Hong Kong and Macau), for a period of 10

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years after obtaining the Class III medical registration of ICervsure (艾宫舒). Outside PRC, we and HybriBio Biotech are entitled to produce, manufacture and sell ICervsure (艾宫舒) under each parties’ respective brand. HybriBio Biotech is one of our Sophisticated Investors. For details on HybriBio Biotech, please refer to “History, Development and Corporate Structure – [REDACTED] Investments – Background of the [REDACTED] Investors – HybriBio Biotech” in this document.

R&D Status

At the time of the Out-licensing Agreement, ICervsure (艾宫舒) was still under development and we had not obtained the Class III medical device registration in mainland China. As we retain the right to register and commercialize ICervsure (艾宫舒) in overseas markets, we obtained CE certification for ICervsure (艾宫舒) in June 2021. In mainland China, the registration and commercialization of ICervsure (艾宫舒) are led by HybriBio Biotech, while we enjoy profit-sharing arrangements. ICervsure (艾宫舒) received NMPA approval in September 2024.

Key Rights and Obligations of the Parties

We are the patent holder and owner of the know-how for ICervsure (艾宫舒), and we have granted HybriBio Biotech an exclusive license to use the relevant patents and a non-exclusive license to use the know-hows in mainland China. Under the Out-licensing Agreement, HybriBio Biotech is obligated to pay royalties and formula usage fees on and in connection with sales of ICervsure (艾宫舒). The formula usage fees are based on sales of ICervsure (艾宫舒) and its ancillary products. The formula usage fee is calculated according to the ex-factory price, sales volume and the applicable royalty rates. The royalty rate is 8% for cumulative sales volumes up to 50,000 tests and 10% for volumes exceeding that threshold. For its ancillary products, a formula usage fee of RMB1.5 per test is payable. Where ICervsure (艾宫舒) is sold to a related party, the transaction price must not be lower than the average price charged to independent distributors; otherwise, the fee is calculated based on the highest price previously sold to hospitals. No separate profit-sharing arrangement is included in the agreement. All such payments are settled on a quarterly basis. The Out-licensing Agreement may be terminated under certain circumstances, including material breaches such as delayed delivery of technical materials, delayed payments, falsification or concealment of sales records, etc. Disputes under the Out-licensing Agreement are to be resolved through consultation or mediation in the first instance, failing which either party may bring proceedings before the competent PRC court. We retain the underlying intellectual property rights in ICervsure (艾宫舒) and the ancillary product, and HybriBio Biotech is granted a license solely for the purposes of the Out-licensing Agreement. Any optimization or improvement developed by HybriBio Biotech based on the licensed product or the ancillary product shall vest in us with rights equivalent to the original intellectual property.

Amendment in March 2019

Following the execution of the agreement in 2018, we and HybriBio Biotech noted uncertainties in the clinical development timeline of ICervsure (艾宫舒) covered by the licensed patents. Under the amended terms, the license period was revised to ten years commencing from the date on which the product obtains regulatory approval, and both parties were granted the right to independently produce, commercialize, and distribute the product in overseas markets under their respective brands.

Payment and Settlement

ICervsure (艾宫舒) was approved for use as HybriBio Biotech’s product in September 2024. Settlement of the corresponding formula service fees with our Company commenced in 2025, and the related income will be calculated based on the audited financial results for 2025. HybriBio Biotech has settled the amount payable for the year 2025.

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Outsourced R&D

To address key downstream scalability challenges, we are developing AMStation, a fully automated sample processing workstation on an outsourced basis. We participated in the design of AMStation while the development and manufacturing process was outsourced to a specialized extraction instrument company. AMStation is designed to handle the pre-analytical stage of testing, allowing for processing up to 60 fecal samples for pre-treatment and extract and transform 16 nucleic acid samples within approximately three hours. Since qPCR equipment is already widely available in most hospitals and compatible with our reagents, AMStation enhances test efficiency by automating front-end sample preparation, ensuring seamless integration with our products. This not only accelerates sample processing but also improves user experience for hospitals and laboratories. By commercializing AMStation alongside our test kits, we can strengthen product synergy, drive broader adoption, and support large-scale clinical application. AMStation is expected to complete the EMC test and safety compliance test and submit its Class I medical device filing application to the Administration for Market Regulation of Wuhan City, Hubei Province in April 2026.

CLINICAL TRIALS

We conduct clinical trials of our new tests to evaluate their clinical efficacy and to obtain the requisite regulatory approvals. In addition, robust clinical data are an important marketing tool for increasing credibility for our brand and tests. The goal of a clinical trial is to validate the performance of our products. Primary parameters for clinical trials are selected based on the intended use of the medical device. As of the Latest Practicable Date, we had two ongoing clinical trials for liver and urothelial cancer recurrence monitoring, respectively, in China.

Collaborations with Clinical Trial Institutions

In accordance with the requirements of the Good Clinical Practice for Medical Devices, we conduct clinical trials of in vitro diagnostic reagents at medical device clinical trial institutions that meet the relevant conditions and have been duly registered. Based on preliminary investigations, we normally select several hospitals from those with completed registrations, rich professional expertise, strong academic and clinical reputations, sufficient patient populations and clinical trial capabilities. Subsequently, we meet with these selected hospitals to discuss the trial protocols and confirm the clinical trial institution.

We typically enter into an agreement with each selected hospital for each clinical trial, under which we and the participating hospitals prepare a clinical trial protocol following GCP standards that describes in detail the goal of the clinical trial, the risks involved, the overall design, the methods and the procedures of the trial. We submit the relevant documents to the ethics committee of each participating hospital for review. Such documents typically include our clinical trial protocol, draft informed consent to be filled out by subjects, draft case report forms to be completed by investigators supervising the clinical trial, and agreement with the hospital to perform the clinical trial. Once the protocol is approved, any amendment thereafter is required to be reviewed and consented by the ethics committees and the clinical trials are required to be conducted strictly pursuant to the approved protocol.

Pursuant to the agreements with participating hospitals as described above, each participating hospital is typically obligated to conduct the clinical trials following the protocol, issue a case report at the end of the trial based on the collected data, and keep trial records for five to ten years after the end of the trial. The research institution typically gathers the case report forms from all participating hospitals and prepares formal reports of the clinical trial. We make payments according to the agreed schedules and items for the hospitals' services. We typically own all related intellectual property and results from the trial. Each participating hospital is typically entitled to publish academic papers or attend academic events using the trial results upon our written approval.

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Relationships with CROs and SMOs

We collaborate with reputable CROs and SMOs for the support of our clinical trials. Our CROs provide services such as the implementation and management of clinical research projects as specified in the master agreement or a work order. Our SMOs provide services such as trial site management and subject enrollment support.

When selecting CROs and SMOs, we consider a number of factors, including their qualifications, track record and professional experience of their employees, in particular, their familiarity with laws and regulations related to IVD products and inclusion in hospital-recognized lists in terms of SMOs. For each new clinical trial, we generally enter into an agreement with the CRO or SMO. We closely monitor our CROs and SMOs to help ensure their performance will comply with all applicable laws and regulations as well as following our protocols, which in turn protects the integrity and authenticity of the data from our clinical trials and studies.

We have worked with CROs and SMOs for our clinical trials, including the clinical trial for IHepcomf (艾馨甘) and IUriSure (艾光樂). For example, under our respective agreements with the CRO and the SMO in relation to the clinical trial for IUriSure (艾光樂), we are responsible for the trial preparation, subject enrollment, trial implementation and management, while the CRO taking the responsibility of clinical trial inspection and the SMO taking responsibility for clinical trial coordination, record keeping to guarantee the compliance of the clinical trial process with applicable regulations or standards and assisting with preparation of clinical trial report. In return for their services, we make scheduled payments as agreed in the agreements. Under the agreements, the CRO and the SMO must maintain strict confidentiality with respect to the information they acquired from us during clinical trials.

Clinical Studies and Relationship with PIs

In addition to our collaboration with clinical trial institutions, CROs and SMOs, we also maintain continuous communications with PIs, physicians and hospitals, who are informed of our latest research and development progress. The PIs we work with not only provide us with important feedback on clinical needs but also present the clinical use of our tests in academic settings, which we believe can invite wider discussion of our products and product candidates and in turn contribute to our research and development efforts. Furthermore, we participate in industry conferences with respect to our research and development efforts and product pipeline. We have presented our tests in multiple industry conferences, where we keep industry participants updated of our latest research and development progress.

MANUFACTURING INFRASTRUCTURE

Our Manufacturing Team

We have a strong and specialized manufacturing team, well positioned to bring proprietary technologies or processes into GMP production. Our manufacturing team is led by Ms. Yu Xin (余昕), who has about 11 years' experience in the management of medical device manufacturing. We provide training to our manufacturing personnel to ensure that they possess the skill sets and techniques required in the relevant manufacturing process, and comply with our quality control requirements as well as applicable laws and regulations.

Manufacturing Facilities

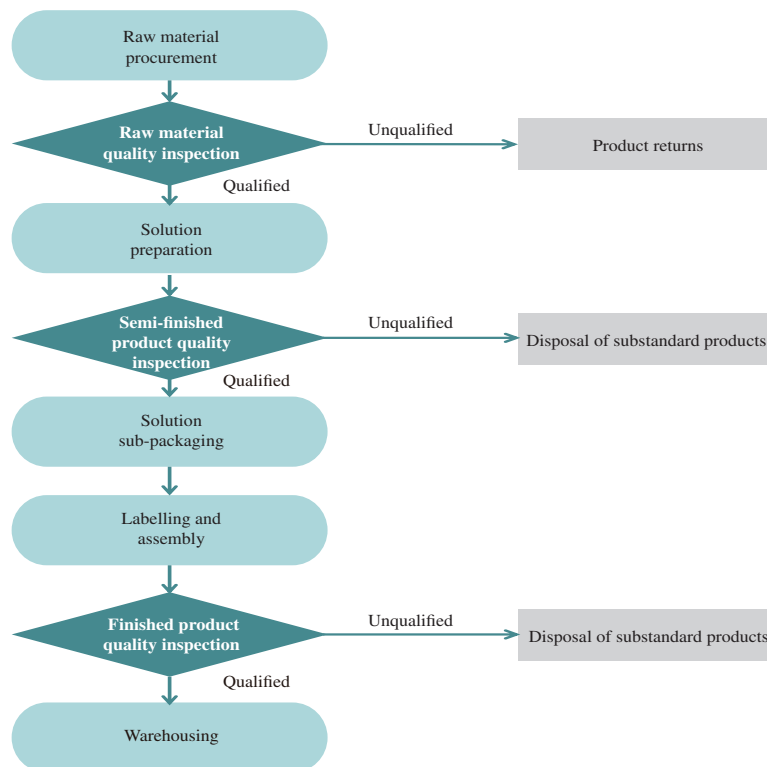
As of the Latest Practicable Date, our principal manufacturing facilities are located at Wuhan, China with an annual production capacity of approximately 1.3 million tests, which was primarily used for the production of our early cancer detection products and product candidates, including IColocomf (艾長康), IColohunter (艾長健), IHepcomf (艾馨甘) and IEsohunter (艾思寧) during the Track Record Period. Our manufacturing facilities are equipped with advanced

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automation, which can significantly improve efficiency and reduce manufacturing costs. The production lines, equipment, and personnel are designed for maximum flexibility and synergy across our product portfolio. Facilities for PCR test kits, nucleic acid extraction and purification kits, and certain instrument products are largely interchangeable, allowing us to share resources such as production lines, labeling, assembly, and staffing. This integrated approach enhances operational efficiency, reduces costs, and enables rapid scaling across both commercialized products and product candidates.

Manufacturing Process

The manufacturing of our early cancer detection products and product candidates primarily involves the following steps:



All the steps in our production process are conducted in compliance with the applicable Good Manufacturing Practice (“GMP”) requirements, and our entire quality management system has been certified to ISO 13485:2016 standards, ensuring consistent delivery of safe, effective, and high-quality medical device products. We have implemented quality management systems as part of our manufacturing processes. For more details, please refer to “– Quality Control” in this section.

We conduct all of the manufacturing process of our reagents and sample collection kits in-house. Our integrated and automated production process increases our production efficiency and reduces our dependence on third parties. This vertical integration also enables us to adjust our production quickly to respond to changes in market demand for our products. In addition, we regularly conduct cleaning and disinfection as required by the applicable standards.

The machines we use to manufacture our products mainly include pipettes, electronic dispensers, biosafety cabinets, electronic balances, magnetic stirrers, automated filling lines and peristaltic pump. We purchase machines from multiple suppliers, and we are able to source such machines from alternative suppliers. We have implemented a comprehensive maintenance system

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for our machinery. During the Track Record Period, we had not experienced any material or prolonged interruptions of our machinery due to equipment or machinery failure.

SALES AND MARKETING

During the Track Record Period, substantially all of our revenue was generated from the sales of our NMPA-approved products, namely IColocomf (艾長康), IColohunter (艾長健), IEsohunter (艾思寧) and IHepcomf (艾馨甘). For details, please refer to “Our Product and Product Pipeline – Commercialized Products” in this section. In addition, most of our revenue was generated in China, with a small portion contributed by overseas sales, during the Track Record Period.

Sales and Marketing Team

Following the launch of our first commercialized product IColocomf in 2022, we increased our marketing headcounts to support market expansion and continuously optimize our marketing team in response to our business needs. As of December 31, 2025, our in-house sales and marketing team consists of 28 members who provides doctors, end-users and other healthcare institutional clients with customized support. Our marketing team is divided into various functions covering different geographic regions and different channels.

We organize trainings for our newly joined sales and marketing personnel before they start the field work. Our training generally includes background introduction of early cancer detection technologies and industry, conditions of markets where we sell our products, and an in-depth analysis of our competing products and competing companies and comparison against our products’ sales status, which enables our employees to appropriately present the features and technologies of our products to customers. The courses we offer include product knowledge training and assessment, hospital channel development and partner selection, investment promotion and negotiation strategies, full-process hospital development management and risk control training, effective bidding and tendering, targeted department profiling for early cancer detection products, communication strategies for early cancer detection products with health checkup groups, effective distributor management, direct hospital operations management and customer payment and receivables management. We also arrange trainings to brief our team the latest changes in the markets, development of our competing products and the marketing progress of our products in the relevant markets.

In line with our strategy to further develop the early cancer detection market in China, our sales and marketing team designs marketing strategies and engages in promotion activities based on respective market conditions, such as competitive landscape and regulatory environment. Our sales and marketing efforts primarily include educating doctors and physicians, or potential end users, at hospitals and health checkup centers, on the advantages of our tests and products and the clinical data supporting our performance. Specifically, each team is responsible for establishing and maintaining relationships with designated hospitals and health checkup centers and promoting the awareness and recognition of our products among doctors and physicians, through academic lectures and other promotional efforts. We prioritize developing business relationship with hospitals, who also collect feedback on our products for further improvement. Besides, our sales team also coordinates with distributors in the promotion and distribution of our products by providing trainings on the early cancer detection industry and benefits and performance of our tests and products. Our management closely oversees the sales activities and results in the major markets and determines the sales and pricing policies in each market.

Marketing Model

We market our early cancer detection products primarily through an network of distributors, while also maintaining direct sales to medical testing laboratories, private health checkup centers and other direct sales channels.

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We promote the awareness of our products through, (i) mass market education, (ii) participating in and sponsoring medical summits, conferences and seminars, (iii) engaging with media and charitable organizations to increase public awareness, and (iv) partnership with hospitals and research institutions. Our marketing efforts are facilitated through both online platforms and offline channels, to our existing customers and potential new customers.

Sales Channels

We market our early cancer detection products primarily through direct sales, while also maintaining an network of distributors. We have established a robust sales and distribution network, covering 90 cities in China as of the Latest Practicable Date, including major cities such as Beijing, Shanghai, Chongqing and Shenzhen.

The following table sets forth a breakdown of our revenue generated from direct sales and sales through distributors:

	For the year ended December 31,			
	2024		2025	
	RMB'000	% of revenue (%)	RMB'000	% of revenue (%)
Direct sales ⁽¹⁾	5,131	71.0	10,597	69.0
Distribution ⁽²⁾	2,107	29.0	4,823	31.0
Total	7,238	100.0	15,419	100.0

Note:

- (1) Revenue generated from direct sales comprises our sales to (a) medical testing laboratories, (b) health checkup centers with testing laboratory, and (d) hospitals that we reached without distributors.
- (2) Our distribution model focuses on hospital end-users. The relatively low distributorship sales were mainly attributable to (a) the fact that prior to September 2024 we marketed only IColocomf, a colorectal cancer methylation detection reagent, resulting in limited overall sales; (b) IColocomf was not among the first products of its kind approved in China and faced competition from similar products, leading to a slower pace in market share increase; and (c) as methylation-based detection was a new and specialized technology, we carefully screened and selected qualified distributors. Professional distributors in this area were generally small in scale and had limited hospital coverage.

Direct Sales

Our direct sales channels mainly include medical testing laboratories and health checkup centers.

Medical testing laboratories

We promote our products at medical testing laboratories. We have formed strategic collaborations with a number of well-established medical testing laboratories across China, which we believe enhances our market reach, especially in scenarios involving physician referrals and diagnostic workflows. These laboratories play a critical role in expanding the accessibility and clinical adoption of our products by integrating them into their routine testing services. For example, we have partnered with KingMed Medical, one of the medical testing laboratory service providers in China.

Under a typical collaboration with medical testing laboratories, the medical testing laboratory incorporates our cancer detection products into its testing service offerings to hospitals and clinics. We normally enter into agreements with medical testing laboratories for a term of one year, which may be renewed through negotiation and execution of a new agreement. We are responsible for ensuring timely delivery and inventory availability to meet their ongoing demand.

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Private health checkup centers

We promote our products at private health checkup centers. We have established solid business collaborations with health checkup centers across China, which we believe enables us to fast penetrate the market with a well-developed end-user base and to promote market acceptance of our early cancer detection products. Health checkup centers also benefit from the convenience and high efficacy of our products. For example, we have promoted our products at iKang (愛康國賓), one of the largest health checkup center chains in China.

Under a typical collaboration with private health checkup centers, the private health checkup center usually designates a medical laboratory which is responsible for assisting us in promoting products through relevant channels and providing customer services. We are responsible for maintaining a basic inventory level for our products to meet the purchase demand from the designated medical laboratory. We typically enter into agreements with the designated medical laboratory for a term of one year, which may be renewed through negotiation and execution of a new agreement. Pursuant to such agreements, the designated medical laboratory may order our products based on demands from its customers, with no minimum order requirement. Such agreements can typically be terminated based on mutual consent from both parties.

Distribution

We cooperate with distributors who purchase our products from us and further distribute our products to public hospitals and primary-level healthcare institutions. Our sales through distributors include sales to customers which (i) we contracted as distributor or promotion agent; (ii) are authorized or obligated to conduct wholesale business of our products; (iii) are authorized or obligated to promote or market our products; or (iv) agreed to share promotion and marketing expenses and fees based on allocation agreed between parties. Our distributors primarily engage in the medical device distribution business. Our sales and marketing team screens and selects distributors whom have the required qualifications and capabilities and are suited to our strategic marketing model, and establishes and maintains resource sharing with our distributors to effectively execute our marketing strategies specifically tailored to each designated geographic location. According to Frost & Sullivan, in the medical device industry, it is customary to use distributors for the sales of medical devices to medical institutions. We believe that our existing distributorship model is consistent with customary industry practice and serves to ensure efficient coverage of our sales network while controlling our cost of distribution.

Selection and Management of Distributors

Upon selecting distributors, we will first evaluate their qualifications. We select our distributors based on their experience in the medical device industry, particularly in early cancer detection products. In addition, they must possess the requisite business licenses and permits to sell medical devices in the respective jurisdiction and have established relationships with hospitals, and health checkup centers and physicians within their designated territory. Before we appoint a distributor, we assess its sales staff and management to help ensure that they have the appropriate educational background and professional skills. We may also consult with the hospitals, health checkup centers, insurance companies, pharmacies or online channels regarding our choice of distributors. We review the qualifications of our distributors when our contracts with them are due to be renewed. The distributor selection criteria and process are as follows. Distributors must meet certain qualification requirements, including holding a valid business license and a medical device operation license, with a business scope that covers the products they will represent. For products requiring cold-chain transportation, distributors must provide the relevant cold-chain transportation qualifications and equipment certification. They should also have no significant legal violations or commercial disputes. In terms of capabilities,

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distributors are expected to possess a well-established sales network in the medical reagent and testing field, covering hospitals, third-party testing institutions, and other end users. They should have a professional sales and technical support team capable of providing on-site services, product training, and after-sales consultation. Distributors must have sufficient financial strength to support inventory and market promotion needs and be willing to comply with our required cooperation models, such as cash-on-delivery or prepayment arrangements. During the Track Record Period, apart from HybriBio Biotech and its certain associates, none of our distributors had any past or present relationship (business or otherwise) with our Group, our shareholders, directors, senior management or any of their respective associates. For details of our relationship with HybriBio Biotech, please refer to “Continuing Connected Transaction” in this document.

We conduct annual review of our distributors, based on their business performance, payment performance, regulatory compliance and end customer comments. Our distributors are generally required to comply with all applicable laws and regulations, such as anti-bribery and anti-kickback laws and regulations, and obtain relevant permits to sell and distribute medical devices. Distributors’ business performance is primarily evaluated based on the distributors’ sales performance, specifically whether they meet the target order amount and minimum purchase amount, and feedbacks from the designated hospitals and health checkup centers. We also review their compliance with applicable laws and regulations. Our sales and marketing department monitors, manages and supports the activities of our distributors to help ensure that they comply with our guidelines, policies and procedures. We generally do not grant any kinds of cash rebates to our distributors. We may grant different incentive and discount to our distributors on a case by case basis, such as giving additional products for free to our distributors if they meet certain sales targets. We retain the discretion to adjust their credit terms, renegotiate order price and certain other commercial terms with them based on the review results.

During the Track Record Period, we generally maintained effective management and control over our distributors. We believe we can minimize the risk of channel stuffing since (a) we generally do not allow return or exchange of our products other than for product quality issues, packaging damage during delivery or incorrect invoicing or shipment; (b) we regularly communicate and conduct review with our distributors primarily regarding their inventory level, sales amount and marketing activities, as applicable; and we also check the actual inventory status at the warehouses of the distributors through ad hoc visits by our designated staff.

To mitigate channel stuffing and competition among distributors, we adopt a single-tier distribution model without sub-distribution which minimizes pricing differences and removes incentives for cross selling. Each distributor signs an agreement with us specifying the term, scope and authorized hospitals. Distributors are required to obtain our written authorization which define the approved products, geographic coverage and validity period, ensuring that distributors sell only within their designated areas and do not compete for the same hospital clients. We also comply with the Rules on the Unique Device Identification System for Medical Devices (《醫療器械唯一標識系統規則》), under which each product is assigned a unique device identification code to ensure full traceability.

Our PCR-based assays have a shelf life of approximately one year. The hospital end-users generally acquire products with at least six months of remaining shelf life, hence reducing the likelihood of overstocking.

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Salient Terms

Our agreements with distributors typically include terms such as the designated distribution area and hospitals, target order amount and credit terms. The typical principal terms are summarized below.

- *Duration and option to renew.* The distribution agreement is typically effective for a period of one year or two years and may be renewed through negotiation and execution of a new agreement.
- *Designated geographical regions.* Distributors are typically authorized to sell our products within a designated region. If distributors are granted exclusive distribution right, except for us engaging in direct operations or sales, we shall not appoint any other distributors to sell our products within the designated distribution territory through any distribution methods or channels.
- *Exclusivity.* The distribution agreement is exclusive for the designated end customers such as hospitals and biotech companies, except for sales conducted by us or our affiliates.
- *Minimum purchase amount.* There is no minimum purchase requirement or minimum sales target.
- *Responsibility of distributors.* Distributors shall be responsible for formulating and implementing the sales strategies and plans for the products.
- *Payment and credit terms.* Sales to our distributors are primarily settled on a prepayment basis, although certain distributors may be granted credit terms ranging from one to six months.
- *Termination.* The distribution agreement may be terminated if the distributor promotes or sells competing products within the authorized scope of distribution.

During the Track Record Period, our distributors did not materially breach our contract terms, and we did not have any disputes with our distributors relating to the settlement of trade receivables. As of the Latest Practicable Date, we were not aware of any potential abuse or improper use of our name by our distributors which could adversely affect our reputation, business operation or financial contribution.

Movement in the Number of Distributors

The below table sets forth the movement in the number of our distributors by geographic region during the Track Record Period.

	Year ended December 31,	
	2024	2025
Number of distributors at the beginning of the year	92	97
Number of new distributors for the year	71	137
Number of distributors who ceased to be our distributors for the year	66	87
Net increase (or decrease) in number of distributors for the year	5	50
Number of distributors at the end of the year	97	147

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For the two years ended December 31, 2024 and 2025, 66 and 87 distributors ceased to be our distributors mainly due the expiry of distribution agreements without renewal or extension. In the IVD industry, professional distributors are generally small in scale and relatively new to the market. Distribution arrangements in the industry are generally short-term. We have made active efforts to test the market and assess the effectiveness of our distributors and continue to streamline our distributor structure.

Despite our expanding sales network and established partnerships, the commercialization of our products has been subject to inherent delays due to regulatory and procedural factors associated with hospital adoption. As our products are classified as Class III medical devices, hospitals must complete a series of pricing registration, network listing, and admission procedures before clinical use, which typically extends over a period of one year or longer. For IVD products based on DNA methylation testing, pricing applications must be jointly submitted with cooperating hospitals, and the approval timelines vary across provinces. These sequential approval procedures have limited the speed of market penetration immediately following product registration.

As our Core Products obtained NMPA approval in 2025, many hospitals are still in the process of completing admission and procurement procedures. Consequently, the contribution of our new products to overall revenue remains modest to date. We expect market adoption and revenue generation to improve progressively as more hospitals complete their admission processes and commence clinical use, supported by our deepening collaborations with hospitals, laboratories, and healthcare institutions across China and overseas.

Return and Exchanges

In general, we do not allow return or exchange of our products, which are provided to users in order to conduct the tests, other than for product quality issues, packaging damage during delivery or incorrect invoicing or shipment. We may consider allowing return or exchange for other special circumstances at our sole discretion. We have adopted and been implementing our Product Return and Recall Policies. All packaging and transportation costs incurred for products returned by our customers to us, as well as for replacement products we deliver to our customers, shall be fully borne by us.

Revenues from provision of our products are recognized when our customers accept our products. We recognize refund liabilities if we expect to refund some or all of the considerations received from customers. During the Track Record Period, we have not recognized any refund liabilities. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material product return from customers.

Pricing

For our direct sales customers, we negotiate the price directly with them on a case-by-case basis. With respect to sales through distributors, generally, our distributors set retail prices directly with their customers, and such retail prices shall conform to the agreed resale prices set in the distribution agreement. We also conduct regular checks on their compliance to our pricing requirements.

OUR CUSTOMERS

Major Customers

For the years ended December 31, 2024 and 2025, sales to our top five customers in aggregate amounted to approximately RMB5.3 million and RMB11.7 million, representing 73.2% and 75.6% of our total revenue, respectively. For the years ended December 31, 2024 and 2025, sales to our largest customer for each year of the Track Record Period were RMB3.8 million and RMB3.9 million, representing 52.1% and 25.3% of our total revenue, respectively. Our major customers generally settle the payment by wire transfer.

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The following table set forth our top five customers for the respective periods indicated:

For the year ended December 31, 2024:

Customer	Background of the customer	Type	Transaction amount <i>RMB'000</i>	% of total revenue %	Nature of revenue	Credit terms	Start year
Wuhan Ainuo Medical Laboratory ⁽²⁾	The Customer is incorporated in the PRC with registered capital of RMB10.0 million, and mainly engaged in biotechnology testing services.	Medical Testing Laboratory	3,774	52.1	Sales of products	90 days	2022
KingMed Medical ⁽³⁾	The Customer is incorporated in the PRC with registered capital of RMB463.3 million, and mainly engaged in IVD services, providing clinical laboratory services. The Customer is listed at Shanghai Stock Exchange, and the stock code is 603882.	Medical Testing Laboratory	674	9.3	Sales of products	90 days	2022
Guangdong Hybribio	The Customer is incorporated in the PRC with registered capital of RMB646.5 million, and mainly engaged in manufacturing of IVD devices, developing, producing and selling high-tech biological detection instruments and reagents. The Customer is listed at Shenzhen Stock Exchange, and the stock code is 300639.	Manufacturer and Distributor	375	5.2	Sales of products, license income	15 days	2020
Linyi Amison Early Screening Life Technology Co., Ltd.* (臨 沂艾米森早篩 生命科技有限 公司) (“Linyi Amison”) ⁽¹⁾	The Customer is incorporated in the PRC with registered capital of RMB0.6 million, and mainly engaged in biotechnology services, providing biotechnology R&D and services.	Biotech Products Distribution	347	4.8	Sales of products	40 days	2023
Customer A	The Customer is incorporated in the PRC with registered capital of RMB20.0 million, and mainly engaged in IVD services, providing IVD services and pharmacy retail.	Biotech Service Provider	133	1.8	Sales of products	90 days	2023
Total			5,303	73.2			

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For the year ended December 31, 2025:

Customer	Background of the customer	Type	Transaction amount RMB'000	% of total revenue %	Nature of revenue	Credit terms	Start year
KingMed Medical ⁽³⁾	The Customer is incorporated in the PRC with registered capital of RMB463.3 million, and mainly engaged in IVD services, providing clinical laboratory services. The Customer is listed at Shanghai Stock Exchange, and the stock code is 603882.	Medical Testing Laboratory	3,904	25.3	Sales of products	150 days	2022
Wuhan Ainuo Medical Laboratory ⁽²⁾	The Customer is incorporated in the PRC with registered capital of RMB10.0 million, and mainly engaged in biotechnology testing services.	Medical Testing Laboratory	2,656	17.2	Sales of products	90 days	2022
Customer B	The Customer is incorporated in the PRC with registered capital of RMB10.0 million, and mainly engaged in detection services, providing clinical detection services.	Biotech Service Provider	2,529	16.4	Sales of products	120 days	2025
Customer C	The Customer is incorporated in the PRC with registered capital of RMB5.0 million, and mainly engaged in IVD services, providing clinical laboratory services.	Biotech Service Provider	1,805	11.7	Sales of products	Full prepayment	2025
Customer D	The Customer is incorporated in the PRC and mainly engaged in detection services, providing clinical detection services.	Biotech Service Provider	768	5.0	Sales of products	90 days	2025
Total			11,662	75.6			

Notes:

- (1) The beneficial owner of Linyi Amison ultimately holding 49% of its equity interest is Mr. Yang Baojin. Mr. Yang is an entrepreneur based in Linyi with knowledge of the local healthcare product market and related policies. Based on business negotiations, Mr. Yang proposed the Company to hold 51% of the equity in Linyi Amison to utilize our Company's brand advantage to facilitate communication with and sales to its downstream customers. The actual operations of Linyi Amison was managed by Mr. Yang who enjoyed the whole operating profits. As of the Latest Practicable Date, our Company holds only 8% of equity interest of Linyi Amison. The remaining 43% of Linyi Amison's equity was transferred and now ultimately held by Mr. Pan Jianyu (潘建宇) through Hubei Ruilin Biotechnology Co., Ltd.* (湖北睿臨生物科技有限公司) which are each an independent third party of our Company.

Linyi Amison is mainly engaged in biotech products distribution. The customer base of Linyi Amison mainly consists of local healthcare institutions in Linyi. The suppliers of Linyi Amison mainly consist of providers of diagnostic kits including our Company. For the years ended December 31, 2024 and 2025, the total revenue of Linyi Amison amounted to RMB0.4 million and RMB0.6 million respectively. For the

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years ended December 31, 2024 and 2025, Linyi Amison has a net loss of RMB0.3 million and RMB0.2 million respectively. To the best of our knowledge, Linyi Amison did not have any material non-compliance or litigation or dispute with third parties during the Track Record Period and up to the Latest Practicable Date.

- (2) Based on the unaudited management accounts, Wuhan Ainuo Medical Laboratory generated total revenue of RMB 12.6 million and RMB 6.6 million for the years ended 31 December 2024 and 2025 respectively. Wuhan Ainuo Medical Laboratory recorded net losses of RMB 2.1 million and RMB 1.2 million for the years ended 31 December 2024 and 2025 respectively.
- (3) The largest shareholder of KingMed Medical is Mr. Liang Yaoming (梁耀銘), who is also the ultimate controlling shareholder of Guangzhou Jinyuan Kuntong Equity Investment Management Co., Ltd.* (廣州金垣坤通股權投資管理有限公司), the general partner of Suzhou Kinghall, our Pre-[REDACTED] Investor.

To the best knowledge of our Directors, except for Wuhan Ainuo Medical Laboratory and KingMed Medical, none of our Directors, their associates or any of our current Shareholders (who, to the knowledge of our Directors, own more than 5% of our share capital) had any interest in our top five customers in any period during the Track Record Period that are required to be disclosed under the Listing Rules. To the best knowledge of our Directors, except for Wuhan Ainuo Medical Testing Laboratory and Guangdong Hybribio, none of the above top five customers are our connected persons under Chapter 14A of the Listing Rules. For details, please refer to “Continuing Connected Transactions” in this document.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any material breach of the contracts with our customers, nor did we have any material disputes with our customers.

CUSTOMER SERVICES

We provide channels for complaints regarding our products. We did not receive any major customer complaints during the Track Record Period.

Our marketing department is responsible for collecting and responding to customer inquiries and complaints, maintaining customer profiles, and implementing customer follow-up and care plans. Quality-related complaints are further reviewed and investigated by our quality department, which confirms the nature of the issue, analyzes root causes, formulates corrective actions, and oversees implementation. If necessary, relevant issues are escalated to the production and R&D departments for technical support and resolution. We utilize after-sales service records and customer satisfaction surveys to monitor service quality. Where applicable, our after-sales team also provides product usage guidance and conducts technical support through our sales and marketing personnel.

We have established procedures to conduct product recalls when necessary. During the Track Record Period and up to the Latest Practicable Date, we have not experienced any material product recalls due to quality issues.

RAW MATERIAL PROCUREMENT

For the production of early cancer detection products and product candidates, our principal raw materials are enzymes, reagents and packaging and labeling materials. We primarily use a limited number of suppliers for our principal raw materials, although there are alternate suppliers available for most of such materials. As of the Latest Practicable Date, our principal suppliers for raw materials of our products are based in China, from whom we purchased raw materials on an as-needed basis.

We generally enter into supply agreements with our principal raw material suppliers. Our agreement with the supplier specifically lists our quality requirements. We will decide whether to accept the supply upon inspecting and examining the materials. Our principal suppliers for raw materials usually provide us with credit terms ranging from 30 to 90 days.

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OUR SUPPLIERS

During the Track Record Period, our suppliers primarily consisted of (i) suppliers of our raw materials for production; (ii) CROs and SMOs, who provide third-party contracting services for research and development; and (iii) suppliers of other materials for research and development activities, machines and equipment for our production.

Selection and Management of Suppliers

We have implemented a structured supplier management procedure to govern the selection and management of our suppliers. This process is jointly managed by our procurement, R&D, and quality assurance departments to ensure that all suppliers meet our requirements for quality, stability, and compliance.

We typically conduct a screening and qualification process on new suppliers, which includes review of required licenses and certifications, sample testing based on internal specifications, and on-site audits when necessary to assess the stability and quality of raw material supplies by such potential new supplier. We also conduct periodic reviews of our suppliers based on their supply performance and regulatory compliance. For details, please refer to “– Quality Control – Quality Control of Raw Material Supply” in this section.

Major Suppliers

For the years ended December 31, 2024 and 2025, purchases from our top five suppliers in aggregate amounted to approximately RMB1.4 million and RMB2.1 million, representing 52.5% and 52.3% of our total purchases, respectively, and purchases from our largest supplier for each year/period of the Track Record Period amounted to RMB0.4 million and RMB0.6 million, representing 15.9% and 15.8% of our total purchases for the same periods, respectively. We generally settle our payment with our major suppliers by wire transfer.

The following table set forth our top five suppliers for the respective periods indicated:

For the year ended December 31, 2024:

Ranking	Supplier	Background of the supplier	Transaction amount <i>RMB'000</i>	% of total purchase %	Product sold or service rendered	Credit terms	Start year
1	Supplier A	The Supplier is incorporated in the PRC with registered capital of RMB172.9 million and paid-in capital of RMB85.6 million, engaged in IVD services, developing and producing biological detection instruments and reagents.	421	15.9	Methylation primer probes and detection reagents	90 days	2017
2	Supplier B	The Supplier is a hospital in Beijing with an initial funding of RMB329.4 million.	341	12.9	Clinical trial	7 days	2023
3	Supplier C	The Supplier is a hospital in Wuhan with an initial funding of RMB258.1 million.	252	9.5	Clinical trial	7 days	2022
4	Supplier D	The Supplier is a hospital in Wuhan with an initial funding of RMB630.89 million.	212	8.0	Clinical trial	7 days	2023

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Ranking	Supplier	Background of the supplier	Transaction amount <i>RMB'000</i>	% of total purchase %	Product sold or service rendered	Credit terms	Start year
5	Supplier E	The Supplier is a hospital in Beijing with an initial funding of RMB1,455.68 million.	163	6.2	Clinical trial	7 days	2023
Total			1,389	52.5			

For the year ended December 31, 2025:

Ranking	Supplier	Background of the supplier	Transaction amount <i>RMB'000</i>	% of total purchase %	Product sold or service rendered	Credit terms	Start year
1	Supplier F	The Supplier is incorporated in the PRC with registered capital of RMB5.0 million, is a non-listed company, and mainly operates in Beijing. Its principal business is clinical testing services.	644	15.8	Clinical trial	7 days	2025
2	Supplier G	The Supplier is incorporated in the PRC with registered capital of RMB112,493,716, is a listed company, and mainly operates in Taizhou. Its principal business is the research, production, and sales of biological reagents and consumables.	516	12.7	Blood collection tube	90 days	2023
3	Supplier A	The Supplier is incorporated in the PRC with registered capital of RMB172.9 million, is a non-listed company, and engaged in IVD services, developing and producing biological detection instruments and reagents.	417	10.2	Methylation primer probes and detection reagents	90 days	2017
4	Supplier H	The Supplier is a hospital in Wuhan with an initial funding of RMB780.1 million. Its principal business is hospital operations.	283	7.0	Clinical trial	7 days	2025
5	Supplier B	The Supplier is a hospital in Beijing with an initial funding of RMB329.4 million.	271	6.7	Clinical trial	7 days	2023
Total			2,132	52.3			

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To the best knowledge of our Directors, none of our Directors, their associates or any of our current Shareholders (who, to the knowledge of our Directors, own more than 5% of our share capital) had any interest in our top five suppliers in any period during the Track Record Period that are required to be disclosed under the Listing Rules. To the best knowledge of our Directors, none of the above top five suppliers are our connected persons under Chapter 14A of the Listing Rules.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any material breach of contracts on the part of our suppliers or delay in delivery of our orders from our suppliers, nor did we have any material disputes with our suppliers.

INVENTORY

Our inventories consist of raw materials, work in progress and finished goods. We maintain sufficient inventory level for our finished goods and our raw materials for testing and production, and such level will vary according to the demand of our customers, sales and production plans. Our raw materials mostly have an expiration period ranging from two to three years. We store substantially all our inventories in Wuhan, China.

Our products are generally sold on a first-in-first-out basis. To reduce the risk of inventory backlogs, we regularly review our inventory level. We also do regular physical inventory counts and stock checks to identify damaged products or expired or near expired products and to dispose of or stockpile these products. Our warehousing and logistics department manages our inventory level by monitoring in real time our production activities and sales orders and also taking into consideration any emerging trends through discussions with our sales and marketing department. Based on this information, the production department develops a production and inventory plan, which is updated on a monthly basis, and places orders with suppliers for any inventory which is expected to decline below targeted levels. Our inventory balance as of December 31, 2024 and 2025 was RMB573.0 thousand and RMB829.0 thousand, respectively. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material shortage of inventory.

QUALITY CONTROL

We maintain a company-wide quality management framework in which our quality assurance department, together with other functional departments including R&D, manufacturing and sales and marketing, devotes substantial efforts and resources to the quality control of our products. We have established and implemented a comprehensive quality control system covering the design, research and development, procurement, manufacturing, testing, inventory, transportation and after-sales service of our products and product candidates. Our management team is actively involved in formulating quality control policies, overseeing internal and external quality performance, and ensuring the effective execution of quality-related activities across all relevant departments. We have implemented stringent quality control procedures in accordance with the requirements of the NMPA and other applicable regulations and standards.

As of December 31, 2025, our quality assurance department consists of four employees. The department is principally responsible for the evaluation of suppliers and the inspection of raw materials, intermediates, semi-finished products and finished products, as well as for the establishment, implementation and continual enhancement of the quality management system. In addition, the department evaluates our design processes, supervising the entire development and manufacturing processes and investigating non-conforming events. The department ensures that all our operations are conducted in strict compliance with applicable regulatory requirements and industry standards through real-time oversight, risk management and the implementation of corrective and preventive measures.

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Quality Control of Raw Material Supply

Prior to entering into supply agreements with our raw material suppliers, we perform a screening and qualification process on potential suppliers. Please refer to “ – Our Suppliers – Selection and Management of Suppliers” in this section. For our raw materials used in production, suppliers are obligated to take measures to comply with our quality control standards on their products and manufacturing process. Each batch of raw materials is inspected and tested by our quality assurance department upon receipt, and we reserve the right to reject or return any items that fail to meet our standards.

In addition, we are entitled to conduct on-site audits at suppliers’ premises to assess and monitor their ongoing compliance with agreed quality assurance requirements, which may take the form of system, process or product audits during the course of supply. We also carry out periodic re-evaluations of approved suppliers based on factors such as material conformity rates, delivery timeliness, service quality and quality management performance. In addition, we conduct off-site information assessments to evaluate suppliers’ performance on a continuous basis. Traceability of raw material supplies is required for our principal suppliers.

Quality Control of Inventory

Our quality assurance department and warehouse personnel jointly undertake responsibilities to help ensure the quality of our raw materials and product inventory. The quality assurance department is responsible for inspecting and testing raw materials and finished products before acceptance into inventory.

The warehouse personnel maintain complete and accurate inventory records to ensure traceability, and are responsible for proper storage, maintenance and inspection of inventory in accordance with specified storage conditions. Designated personnel regularly inspect inventory items, including monitoring temperature and humidity for products and raw materials requiring cold-chain or other special storage, and take timely corrective actions in case of deviations.

Quality Control for Manufacturing

Our quality assurance department supervises quality control over the manufacturing process to ensure compliance with applicable regulatory and industry standards, including by performing on-site monitoring and in-process quality control. During manufacturing, cleaning and maintenance procedures are implemented to prevent contamination or cross-contamination. Environmental monitoring, such as dust, microbiological, pressure differential, temperature and humidity tests, is carried out in accordance with our manufacturing standards. Each batch of products undergoes inspection and testing before release. Certain work-in-progress and semi-finished products are also inspected at designated stages. For details, please refer to “– Manufacturing Infrastructure – Manufacturing Process” in this section. Our quality assurance department reviews manufacturing records, laboratory control records and other documentation affecting product quality, and determines whether a product meets our standards for release. Non-conforming products are handled in accordance with our non-conforming product control procedures.

Quality Control for Transportation

Our quality assurance department monitors the transportation process and maintains transportation records, while our sales and marketing department provides customer communication and technical support. We generally engage third-party logistics service providers under shipment agreements, and designated logistics personnel manage the cold-chain transportation of certain products to ensure compliance with required storage and transportation conditions.

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Quality Control for Customer Service

We seek to trace our products sold to customers to the extent practicable. Feedback from customers is collected and analyzed, and customer complaints regarding product quality are handled in accordance with our complaint handling procedures. Quality complaints, whether verbal or written, are documented and investigated, and designated staff are responsible for responding to complaint calls. Where products do not meet quality standards, we replace them at our own cost. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material product returns or product liability claims.

INTELLECTUAL PROPERTY

Intellectual property rights are important to our business. Our future commercial success depends, in part, on our ability to obtain and maintain patents and other intellectual property and proprietary protections for commercially important technologies, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

As of the Latest Practicable Date, we owned (i) 81 registered patents in China, including 59 invention patents, 19 utility model patents and three industry design patents; (ii) one registered patent in U.S.; (iii) 78 patent applications pending registration in China and (iv) two patent applications pending registration in Europe. As of the Latest Practicable Date, we had a total of 18 invention patents and patent applications in respect of IHepcomf, comprising 10 registered patents in China and 8 applications pending approval, including 7 in China and 1 in Europe. As of the Latest Practicable Date, we had a total of 18 invention patents and patent applications in respect of IUriure, comprising 11 registered patents and 7 applications pending approval, all filed in China. As of the Latest Practicable Date, we self-owned all of our material patents as well as patent applications and had no co-own or co-share arrangements of our patents and patent applications with third parties in terms of our material patents and patent applications.

The following table summarizes the details of our patents which represent proprietary biomarkers and technologies specifically discovered and applied for and on IHepcomf and IUriure as of the Latest Practicable Date:

Patent Name	Relevant Core Product	Patent Type	Right Holder	Jurisdiction	Patent Status	Right Expiration Date	Patent Number
A Nucleic Acid Combination, Detection Kit, and Use Thereof for Diagnosing or Assisting in Diagnosing Liver Cancer (一種肝癌診斷或輔助診斷的核酸組合、檢測試劑盒及其應用)	IHepcomf (艾馨甘)	Invention	Our Company	PRC	Effective	2041/06/02	ZL202110605465.X ⁽¹⁾
An Emulsifier for Nucleic Acid Extraction, a Lysis-Binding Solution Containing the Same, a Nucleic Acid Extraction Kit, and Uses Thereof (核酸提取用乳化劑、含有該乳化劑的裂解結合液和核酸提取試劑盒及其應用)	IHepcomf (艾馨甘)	Invention	Our Company	PRC	Effective	2041/05/14	ZL202110529427.0

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Patent Name	Relevant Core Product	Patent Type	Right Holder	Jurisdiction	Patent Status	Right Expiration Date	Patent Number
Use of Liver Cancer Markers in Preparing Liver Cancer Detection Products and a Detection Kit Thereof (肝癌的標記物在製備肝癌檢測產品中的用途及檢測試劑盒)	IHepcomf (艾馨甘)	Invention	Our Company	PRC	Effective	2041/12/22	ZL202111582152.3 ⁽¹⁾
A Nucleic Acid Combination, Detection Kit, and Use Thereof for Diagnosing or Assisting in Diagnosing Liver Cancer (一種肝癌診斷或輔助診斷的核酸組合、檢測試劑盒及其應用)	IHepcomf (艾馨甘)	Invention	Our Company	PRC	Effective	2041/06/02	ZL202211011165.X ⁽¹⁾

The following table summarizes the details of our patent applications in connection with our Core Product as of the Latest Practicable Date:

Patent Application Number	Patent Name	Relevant Core Product	Patent Type	Patent Applicant	Jurisdiction	Patent Application Date	Patent Status
202211619114.5 ⁽²⁾	Reagents for detecting the methylation level of molecular markers and a detection kit for urothelial cancer (檢測分子標誌物甲基化水準的試劑及尿路上皮癌檢測試劑盒)	IUrisure (艾光樂)	Invention	Our Company	PRC	2022/12/14	Pending
EP22815291 ⁽¹⁾	NUCLEIC ACID COMBINATION FOR LIVER CANCER DIAGNOSIS OR AIDED DIAGNOSIS, TEST KIT, AND APPLICATION	IHepcomf (艾馨甘)	Invention	Our Company	Europe	2022/05/31	Pending

Notes:

- (1) ZL202110605465.X, ZL202111582152.3, ZL202211011165.X, and EP22815291 cover the biomarkers used in our IHepcomf product. These patents protect the use of nucleic acid primer and probe combinations targeting the core methylation regions of the GNB4 and Riplet genes in the preparation of liver cancer detection assays. The current level of patent protection is adequate to construct sufficient technical barriers against competitors.
- (2) 202211619114.5 relates to the specific biomarker used in our IUrisure product, namely the AL021918.2 gene methylation. Based on our proprietary research, the use of AL021918.2 gene methylation for the detection of urothelial carcinoma was first identified by us, and no earlier publications have been found. This patent application protects the key region of the AL021918.2 gene, and once granted, it will provide strong exclusivity, and is adequate to prevent competitors from performing tests targeting this region for the diagnosis of urothelial carcinoma.

As advised by our IP Legal Advisors, our pending patent applications for Core Products are considered ancillary compared to the issued patent. Therefore, our IP Legal Advisors are of the view that whether these patent applications will be granted will not materially affect the fact that our Core Products have already received sufficient patent protection through the registered patents held by us. As of the Latest Practicable Date, none of these patent applications had been

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finally rejected by the applicable patent offices. As of the Latest Practicable Date, except that these patent applications remained subject to the examination opinions from the applicable patent offices during the ordinary pendency and examination of such patent applications, there were no other circumstances to our knowledge that could prevent these patent applications from being granted. However, we cannot guarantee that additional patents for our Core Products will be issued regarding any pending patent applications or future patent applications.

The table below lists the portfolio of the intellectual property rights in connection with our key technologies as of the Latest Practicable Date:

Covered key technology	Patent/Software name	Jurisdiction (country/ region)	Patent type	Right holder	Status	Right Expiration Date	IP No.
iTBFinder database	Tumor Marker Screening Software V1.0 (腫瘤標誌物 篩選軟體V1.0)	PRC	N/A	Our Company	Effective	2070/10/26	2021SR0042982
	Methylation-specific PCR primer design Software V1.0 (甲基化特異性PCR引物設計 軟件V1.0)	PRC	N/A	Our Company	Effective	2072/05/20	2022SR1344457

The term of an individual patent may vary based on the countries/regions in which it is granted. In most countries and regions in which we file patent applications, including China and the United States, the term of an issued invention patent is generally ranging from 10 years to 20 years from the filing date of the earliest non-provisional patent application on which the patent is based in the applicable country. In the United States, a patent’s term may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for administrative delays by the United States Patent and Trademark Office, or USPTO, in excess of a patent applicant’s own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly-owned patent having an earlier expiration date.

The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extension or adjustment, the availability of legal remedies in a particular country/region and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our patents or any such patents that may be issued in the future will be commercially useful in protecting our product candidates and methods of manufacturing the same.

Throughout the Track Record Period and up to the Latest Practicable Date, we had not received any complaints regarding IP rights infringement, and our product candidates had not been subject to any claims, litigations, or investigations concerning any IP issues. In addition, we have performed freedom to operate (“FTO”) analysis of our Core Products, the result of which indicates that there is no material infringement risk for us following the scheduled development and commercialization process of our Core Products in China and the EU. FTO analysis is a patent investigation, based on a search of patent databases, which is commonly used to determine whether any existing patents cover a company’s product, and whether that product would infringe any existing patents. As such, from IP perspective, we can conduct research and development and commercialization of our Core Products without material infringement risks in China and the EU. However, we cannot provide any assurance that

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all relevant third party patents were identified or that conflicting patents will not be issued in the future. Please refer to “Risk Factors – Risks Relating to Our Intellectual Property Rights” in the document.

We may rely, in some circumstances, on trade secrets and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with advisors and contractors. We have entered into confidentiality agreements and non-competition agreements with members of our senior management and certain key members of our research and development team and other employees who have access to trade secrets or confidential information in relation to our business. Our standard employment contract contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee’s work.

As these agreements may not provide sufficient protection of our trade secret and/or confidential information, we also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. Refer to “Risk Factors – Risks Relating to Our General Operations – Our internal computer systems may fail or suffer security breaches.”

We also own a number of registered trademarks and pending trademark applications. We conduct our business under the tradename “Ammunition” (“艾米森”). As of the Latest Practicable Date, we had registered trademarks for our Company and our corporate logo in China and other jurisdictions and are seeking trademark protection for our Company and our corporate logo in other countries where available and appropriate.

During the Track Record Period and up to the Latest Practicable Date, we were not involved in any material proceedings in respect of, and we had not received notice of any material claims of infringement of, any intellectual property rights that are threatened or pending, in which we may be a claimant or a respondent. For details, please refer to “Statutory and General Information – B. Further Information about Our Business – 2. Intellectual Property Rights” in Appendix V in this document.

COMPETITION

The oncology molecular testing market in which we operate is characterized by rapid changes resulting from technological advances and scientific discoveries. In addition, it is subject to changes in the overall healthcare industry in China and globally. While we believe that our product development experience and research and development, testing and manufacturing capabilities provide us with competitive advantages, we face potential competition from various sources, including major international as well as domestic companies which are also developing early cancer tests. For details of our competitors and key competitive advantages, see “Industry Overview – DNA Methylation as a Modality in Cancer Molecular Testing” in this document.

Several of our competitors may have significantly greater financial and other resources and may have longer track records and greater expertise in research and development, clinical trial, obtaining regulatory approvals and commercialization of approved products and may enjoy wide brand name recognition globally. Mergers and acquisitions in the medical device industry may result in even more resources being concentrated among a small number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel,

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establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies or products complementary to, or necessary for, our products.

For the competitive landscape of our products and product candidates, please refer to “–Our Product and Product Pipeline” in this section and “Industry Overview” in this Document.

EMPLOYEES

As of December 31, 2025, we had 92 employees in total, and the majority of our employees were based in China. The following table sets forth the number of our employees categorized by function as of December 31, 2025.

Function	Number
R&D	40
Management	2
Finance and Administration	10
Sales and Marketing	28
Production and Quality Assurance	12

In compliance with the applicable labor laws, we enter into individual employment contracts with our employees covering matters such as wages, bonuses, employee benefits, workplace safety, confidentiality obligations, non-competition and grounds for termination. These employment contracts typically have terms of three years.

To remain competitive in the labor market, we provide various incentives and benefits to our employees. We invest in continuing education and training programs, including internal and external training, for our management staff and other employees to upgrade their skills and knowledge. We also provide competitive salaries, project and stock incentive plans to our employees especially key employees.

We require all of our employees, especially those involved in sales and marketing and business development activities, to abide by our anti-bribery and anti-corruption compliance requirements and applicable laws and regulations to eliminate bribery and corruption risks. We closely monitor our employees’ compliance with anti-bribery and anti-corruption policies.

We do not have any fraud, corruption or unfair competition incident or our employees during the Track Record Period and up to the Latest Practicable Date.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes, labor disputes or industrial actions which had a material effect on our business, and we consider our relations with our employees to be good. During the Track Record Period, we did not make adequate social insurances and housing provident fund contributions for certain employees. Our social insurance contributions shortfall amounted to approximately RMB2.1 million and RMB1.7 million in the year ended December 31, 2024 and 2025 respectively. As advised by our PRC Legal Advisors, under the premise that there have been no significant changes in the policies on social insurance contributions and enforcement and supervision requirements by the relevant government authorities, and no material complaints from employees, the likelihood that we would be required by relevant authorities to make a centralized supplementary payment for any historical shortfalls for social insurance and housing provident fund contributions due to failure to make full contributions is remote.

During the Track Record Period, we did not receive any notification from the relevant PRC authorities requiring us to pay any shortfall in social insurance contributions or imposing any administrative penalties on us with respect to such contributions, nor were we aware of any

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material employee complaints or involved in any material labor disputes with our employees in this regard. We are in the process of rectification and will make full social insurance contributions in compliance with applicable PRC laws and regulations prior to the listing. According to the Interpretation (II) of the Supreme People’s Court on Several Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)), promulgated by the Supreme People’s Court on July 31, 2025 and effective from September 1, 2025, if an employer and an employee agree, or if an employee undertakes to the employer, that social insurance contributions are not required to be paid, the People’s Court shall determine such an agreement or undertaking to be invalid. However, this judicial interpretation does not repeal the existing and effective social insurance laws and regulations in China. As the relevant employees have not entered into any agreement with us to exempt it from paying social insurance contributions, the implementation of this judicial interpretation is not expected to have any material adverse impact on our business, financial condition, or results of operation.

In addition, during the Track Record Period, we engaged third-party human resource agencies to make social insurance and housing provident fund contributions for certain employees. Our PRC Legal Advisors are of the view that, under the premise that there have been no significant changes in the policies on social insurance contributions and enforcement and supervision requirements by the relevant government authorities, and such third-party agency fulfills its obligations to make social insurance and housing provident fund contributions for the relevant employees and no major complaints from employees, and we comply with the requirement within a prescribed period if being ordered by the relevant government authorities, the likelihood that we would be being subject to material administrative penalties in relation to our arrangement of paying social insurance and housing fund contributions for some employees through third-party human resources service agencies is remote.

Based on the foregoing, our Directors are of the view, and the Joint Sponsors, after considering the view of our PRC Legal Advisors, concur with the Directors’ view that the such issues are not expected to have a material and adverse impact on the Group’s financial position or operations. Please refer to “Risk Factors – Risks Relating to Government Regulations – We face certain legal and regulatory risks relating to labor-related laws and regulations, which may adversely affect our business and our results of operations.”

Employment Agreements with Key Management and Research and Development Staff

We enter into standard confidentiality and employment agreements with our key management and research and development staff. The contracts with our key personnel typically include a standard non-compete agreement that prohibits the employee from competing with us, directly or indirectly, during his or her employment and for at least two years after the termination of his or her employment. Employees also sign acknowledgments regarding assignment of inventions and discoveries made during the course of his or her employment. For further details regarding the terms of confidentiality and employment agreements with our key management, please refer to “Directors and Senior Management”.

None of our employees are currently represented by labor unions. We believe that we maintain good working relationships with our employees and we did not experience any significant labor disputes or any significant difficulty in recruiting staff for our operations during the Track Record Period and up to the Latest Practicable Date.

Training and Development

We provide formal and comprehensive company-level and department-level training to our new employees, followed by on-the-job training. We also provide training and development programs for our employees from time-to-time to ensure their awareness and compliance with our various policies and procedures. Some of the training is conducted jointly by departments serving different functions but working with or supporting each other in our day-to-day operations.

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INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. We maintain social welfare insurance for our employees in accordance with relevant PRC laws and regulations, and we also maintain commercial insurance for our employees. We purchase group insurance policies for our end users who purchase and use our products. The end users would be eligible for a claim if a false negative result is produced. We currently do not maintain product liability insurance. We are currently looking for opportunities to acquire product liability insurance.

OUR PROPERTIES AND FACILITIES

As of the Latest Practicable Date, we leased two properties in the PRC with an aggregate gross floor area of approximately 4,146.7 sq.m. both from Independent Third Parties. Our lease agreements in respect of the abovementioned leased properties generally have lease terms ranging from one year to three years. The properties we leased are primarily used for office, R&D and manufacturing purposes.

As of the Latest Practicable Date, two of our lease agreements in the PRC were not registered with the relevant competent authorities. We have taken proactive steps to register these lease agreements. As the registration of a lease agreement requires the cooperation between the lessor and lessee, and lessors are typically unwilling to undertake the administrative burden, we were not able to complete the registration of the relevant lease agreements. Pursuant to the applicable laws and regulations in China, property lease agreements for leased properties must be registered with the relevant real estate administration bureaus in China. As advised by our PRC Legal Advisors, we may be ordered by the relevant government authorities to register the relevant lease agreements within a prescribed period, failing which we may be subject to fines from RMB1,000 to RMB10,000 for each such lease agreement for failure to register. During the Track Record Period and up to the Latest Practicable Date, we have not received any order from the relevant government authorities requiring us to register these lease agreements, and we had not been subject to any material penalties arising from the non-registration of our lease agreements, and had not experienced any dispute arising out of, or in relation to, our leased properties. We consider that suitable replacement premises could be secured with minimal operational impact if required. In view of the above, we and our PRC Legal Adviser believe that this issue does not and will not have any material adverse impact on our business operations. Having considered the views of our Directors, and as supported by our PRC Legal Adviser, nothing has come to the attention of the Joint Sponsors for them to cast doubt on the reasonableness of our Directors’ views expressed above.

As of the Latest Practicable Date, we had no owned property interest that forms part of our non-property activities that has a carrying amount of 15% or more of total assets pursuant to Rule 5.01(2)(b) of the Listing Rules.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE

Overview

We adhere to the core values of “focusing on the needs of diagnosis and treatment, and regarding dedicated innovation as fundamental” to actively promote sustainable development management practices and fulfill our corporate social responsibilities. In accordance with Appendix C2 of the *Listing Rules*, we are formulating an Environmental, Social and Governance (ESG) policy, which will include: (i) ESG work procedures; (ii) ESG risk management and oversight matters; (iii) ESG management principles; (iv) ESG risk management response measures; and (v) identification and analysis of related key performance indicators.

ESG Governance Structure

The Company is committed to establishing an efficient and well-structured board governance system, upholding ESG principles and practicing the concept of sustainable development. The Company’s ESG governance structure consists of three tiers with clearly

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defined roles and responsibilities: The Board of Directors serves as the core decision-making and oversight body, responsible for formulating the ESG development strategy, steering the direction, and managing risks. Senior management acts as the coordinating hub, breaking down the ESG strategy into actionable management measures, facilitating cross-departmental collaboration, and driving implementation. Functional and business departments, including Administration and Human Resources, Information Technology, Production, and Quality, serve as the execution level, integrating ESG principles into daily operations and ensuring that ESG practices are embedded across business processes through departmental coordination.

To achieve efficient management of ESG-related matters, the Company plans to establish a dedicated ESG working group under the framework of the Board committees after listing so as to advance and promote the Company’s ESG initiatives and implementation.

ENVIRONMENTAL

Environmental Protection

We strictly comply with the *Environmental Protection Law of the People’s Republic of China* (《中華人民共和國環境保護法》) and other applicable laws and regulations relevant to the medical industry, and carry out environmental management in accordance with standards such as the *Integrated Emission Standard of Air Pollutants* (《大氣污染物綜合排放標準》) and other environmental protection regulations.

In practice, we actively provide training on environmental protection regulations to enhance employees’ environmental awareness and risk response capabilities. It promotes green office practices such as LED energy-saving lamps and strengthens energy-saving management. A sound environmental management system and emergency response plan for environmental incidents are established. We reduce resource and consumable consumption by developing new technologies and optimizing reagent processes. As of the Latest Practicable Date, we have not been subject to any administrative penalties for non-compliance with environmental protection requirements.

The wastes generated by the Company during its production and operation mainly include wastewater, waste liquid, waste gas and solid waste, and medical waste is not involved. Our production processes do not generate wastewater; wastewater from daily operations is treated and discharged in accordance with the influent water quality requirements of sewage treatment plants. Waste gas generated during production is treated in accordance with the Integrated Emission Standard of Air Pollutants (《大氣污染物綜合排放標準》). We strictly comply with the requirements of the National Catalogue of Hazardous Wastes (《國家危險廢物名錄》) and the Measures for the Administration of Hazardous Waste Transfer Manifests (《危險廢物轉移聯單管理辦法》). For biological materials and hazardous chemicals involved in our production and research and development processes, we implement stringent physical segregation and classified collection measures. Hazardous waste, reagent waste liquids, cleaning waste liquids from solution preparation processes, and the consumables and packaging materials that come into contact with them are stored separately, collected and transported by a qualified third-party service provider, and disposed of in a harmless and professional manner. The entire process is conducted in compliance with regulations without any illegal discharge, effectively eliminating the risk of secondary environmental pollution. In daily laboratory management, the Company implements strict physical separation and operational protocols. Personnel and material flows are segregated to prevent cross-contamination. A color-coded lab coat management system is in place, requiring the use of different colored lab coats in different laboratory rooms, thereby rigorously controlling internal contamination at the source. This effectively mitigates potential contamination risks and ensures comprehensive and standardized environmental management procedures. Over the past three years, we have maintained a consistent record of environmental compliance, with no issues such as pollutant exceedances or illegal discharges. We have

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achieved full zero-pollution compliance in the use and disposal of hazardous substances and biological materials.

As of the Latest Practicable Date, we had not experienced any major incidents arising from improper waste management. Based on the principle that responsibility is transferred but not eliminated, our discharge of the “three wastes” for the years ended December 31, 2024 and 2025 was as follows:

Indicator	Unit	2024	2025
Total Wastewater Discharge	ton	134.00	215.00
Wastewater Discharge Intensity	ton/RMB’000 revenue	0.0185	0.0139
Total Waste Gas Emissions	kg	9.03	9.035
*Non-methane Total Hydrocarbons (NMTHC) in organic waste gas			
Waste Gas Emission Intensity	kg/RMB’000 revenue	0.0012	0.0006
*Non-methane Total Hydrocarbons (NMTHC) in organic waste gas			
Total Hazardous Waste Generated	kg	92.20	64.20
Hazardous Waste Generation Intensity	kg/RMB’000 revenue	0.0127	0.0042

Resource Management

Our energy consumption in the course of production and operations includes the direct and indirect energy consumption. Direct energy consumption primarily refers to gasoline used by vehicles for our daily operations, while indirect energy consumption refers to electricity purchased externally. In recent years, the Company has continuously optimized its production processes, and has been improving the overall energy utilization level through measures such as reducing production batches and enhancing energy efficiency per unit of production capacity. For the years ended December 31, 2024 and 2025, our energy consumption was as follows:

Indicator	Unit	2024	2025
Direct Energy			
– Gasoline	ton	1.07	1.29
Indirect Energy			
– Purchased Electricity	kWh	263,118.00	246,402.00
Total Energy Consumption			
*Direct energy converted based on calorific value	kWh	275,919.00	261,835.42
Energy Consumption Intensity	kWh/RMB’000 revenue	38.13	16.98

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Our water consumption in the course of production and operations is primarily used for solution preparation (配液) in production processes and daily operations. The Company continuously focuses on water use efficiency, emphasizes water conservation, reduces unnecessary waste through process optimization and daily management, and ensures the rationality of water resource utilization in production and operations. For the years ended December 31, 2024 and 2025, our water consumption was as follows:

Indicator	Unit	2024	2025
Total Water Consumption	ton	1,014.00	1,020.00
Water Consumption Intensity	ton/RMB'000 revenue	0.14	0.07

Climate Change

We place high importance on the management of climate-related risks, assess various categories of climate risks, and formulate contingency measures for those with significant impact, thereby continuously strengthening our resilience in responding to climate risks. Our greenhouse gas emissions during daily production and operations primarily arise from: (i) direct GHG emissions generated by vehicles used for daily operations; (ii) energy consumption from purchased electricity for production and business activities; and (iii) indirect GHG emissions from other business activities. For the years ended December 31, 2024 and 2025, our GHG emissions were as follows:

Indicator	Unit	2024	2025
Scope 1 GHG Emissions – Direct GHG Emissions			
– Gasoline	tCO ₂ e	3.13	3.77
Scope 2 GHG Emissions – Energy Indirect Emissions			
– Purchased Electricity	tCO ₂ e	81.57	76.38
Scope 3 GHG Emissions – Other Indirect Emissions			
– Employee Business Air Travel	tCO ₂ e	18.05	18.11
Total GHG Emissions	tCO ₂ e	102.74	98.27
GHG Emission Intensity	tCO ₂ e/RMB'000 revenue	0.0139	0.0064

Taking into account our historical operating performance as well as future business development and production plans, and under the principle of balancing business growth with environmental protection, we have established the following future GHG emission reduction targets:

Indicator	Target for 2026–2028
GHG Emission Intensity	Cumulative not exceeding 0.05

To achieve our future goals, we will reduce energy consumption in production and operations and effectively lower greenhouse gas emissions by optimizing production technologies and processes, expanding the use of new energy vehicles, and other measures.

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SOCIAL

Labor Management

We strictly comply with the *Labor Law of the People’s Republic of China* (《中華人民共和國勞動法》), the *Labor Contract Law of the People’s Republic of China* (《中華人民共和國勞動合同法》) and other applicable laws and regulations. We have established internal policies such as the *Employee Handbook Management System* (《員工手冊管理制度》) and the *Recruitment Management Procedures* (《招聘管理規程》) to ensure compliance in employment practices and protect employees’ rights. We strictly observe the *Provisions on the Prohibition of Using Child Labor* (《禁止使用童工規定》), prohibit the employment of child labor and forced labor and prevent illegal employment practices. As of December 31, 2025, our female employees accounting for approximately 65.22% of the total workforce and a relatively high proportion of female employees in middle- and senior-level management positions. The Company achieved a 100% labor contract signing rate among employees. Employees from Central China accounted for 77.17% of the total workforce, while the remaining employees came from North China, East China, South China, Southwest China, and Northwest China. In terms of employee age structure, 36.96% of employees were aged 30 or below, and 63.04% were between 31 and 49 years old. In addition, we actively support the employment of persons with disabilities, ensuring that they are provided with suitable positions and fair treatment.

We have established a sound and effective occupational health and safety management system and formulated the *Personnel Health Management Procedures* (《人員健康管理規程》). We purchase employer’s liability insurance for field staff, provide annual health examinations for employees, and equip production workshops with protective equipment and emergency devices. In addition, we actively conduct occupational health and safety training, and the training coverage maintained at 100%. For employees who may be exposed to strong acids and alkalis such as hydrochloric acid, we provide specialized training and implement hazardous chemicals assessments. For biological materials and hazardous chemical substances involved in laboratories and workshops, we have not only equipped the workshop with emergency flushing devices and dedicated personal protective equipment, but have also implemented a strict system of pre-employment and quarterly training and assessment to ensure that operators possess the capability to handle potential chemical risks, effectively reducing safety hazards such as biological exposure. As of the Latest Practicable Date, we had not experienced any major safety incidents, nor any work-related fatalities.

We attach great importance to talent cultivation and development, and have established a systematic employee training and development mechanism. Internal policies such as the *Professional Title Management System* (《職稱管理制度》) and the *Training Management Procedures* (《培訓管理規程》) have been formulated. Each department develops employee training plans, with training content covering safety protection, job skills, quality systems, medical device regulations and laboratory management, targeting employees in key functions including R&D, production and quality. The pass rate of training assessments has remained at a high level. For the years ended December 31, 2024 and 2025, our training coverage rate were 100.00%, and the average employee training hours were as follows:

Category	Type	Unit	2024	2025
Gender	Male Employees	hours	12	24
	Female Employees	hours	12	24
Position	Senior Management	hours	12	24
	Middle Management	hours	12	24
	General Staff	hours	12	24

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Healthcare Accessibility

We are committed to improving the accessibility of our cancer early detection products (癌症早篩產品) by expanding into lower-tier markets and ensuring that more people can obtain affordable, high-quality medical services. Through measures such as price adjustments, channel and market expansion, and optimization of technologies and services, we actively implement the concept of “universal healthcare” (普惠醫療).

Since 2024, we have reduced product prices significantly, alleviating the economic burden on patients.

We have also promoted cooperation with health management companies to provide special cancer service packages for insurance companies (保險公司特供版癌症服務包), and launched cooperation with health management companies, under which thousands of pan-cancer tests have already been conducted.

Supply Chain Management

We have established a comprehensive supply chain management system that integrates the concept of sustainable development into all aspects of our supply chain, while ensuring that procurement activities deliver the right products at the right time, in the right quantity, at reasonable prices and with reliable quality. We have formulated the *Procurement Management System* (《採購管理制度》) and the *Supplier Management Procedures* (《供應商管理規程》), which clearly define the systematic and standardized processes for procurement, covering the entire cycle from material demand, supplier sourcing and evaluation to daily management. Suppliers and procurement items are classified and categorized based on material types and procurement scale, in order to minimize supply chain risks.

The Company adheres to the principle of “sunshine procurement,” striving to establish a fair, impartial and transparent procurement environment. Suppliers are required to sign an Anti-Commercial Bribery Agreement (《反商業賄賂協議》) upon contract execution to safeguard our economic interests and prevent misconduct.

Product Responsibility and Customer Service

We strictly comply with the *Regulations on the Supervision and Administration of Medical Devices* (《醫療器械監督管理條例》) and have obtained ISO 13485 medical device quality management system certification and passed annual supervisory audits.

We have established a customer service system, including customer satisfaction surveys, as well as policies such as the *Customer Property Management Procedures* (《客戶財產管理規程》) and the *Complaint Handling Control Procedures* (《投訴處理控制程序》). A dedicated department is responsible for handling inquiries and complaints, with multiple complaint channels available including telephone, email and system feedback.

For the management of non-conforming products, we identify issues in advance, isolate, analyze causes once confirmed, and evaluate the risks and severity involved, ultimately resolving them through rework, scrapping or return, thereby ensuring closed-loop management. As of the Latest Practicable Date, we had not experienced any major quality or safety incidents, and the existing mechanisms have effectively ensured product quality and the protection of customer rights. The number of product recalls due to safety or health reasons is zero.

In bioethical risk management, we strictly adhere to the *CIOMS Guidelines* (《國際醫學科學組織理事會倫理準則》) and the *Universal Declaration on Bioethics and Human Rights*, (《世界生物倫理與人權宣言》) establishing a robust compliance framework for clinical samples and biological data. Our ethical principles and conduct standards cover the entire process from project initiation and research execution to application of results. All patients receive education

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on the potential risks of investigational treatments. We strictly uphold informed consent and patient privacy, ensuring no additional discomfort during sample collection. For specifically collected samples, we provide compensation after communication with patients. Residual samples are obtained from hospital post-experimental specimens and processed in strict compliance with bioethical approval procedures. Our R&D Department oversees clinical trials and collaborates with clinical institutions to ensure compliance in sample collection, data transmission, and ethical review. Partner hospital ethics committees are responsible for approval and supervision, while the Company follows unified bioethical documentation to ensure traceable and compliant sample sourcing.

Access to human genetic fragments and biological data is strictly controlled through tiered permissions, restricted to the R&D Department and project managers, and stored on internal servers to mitigate leakage risks. By fully complying with the *Data Security Law of the People’s Republic of China* (《中華人民共和國數據安全法》) and relevant medical privacy regulations, we have achieved deep integration of bioethical compliance, data security, and privacy protection. As of the latest practicable date, no ethical violations, data breaches, privacy infringements, or related administrative penalties have occurred.

Community Investment

We place great importance on and actively fulfill our corporate social responsibility by continuously investing in medical philanthropy, educational support and community care through financial donations, charitable cancer detection, health education and volunteer services. As of the Latest Practicable Date, our ESG contributions covered medical detection, elderly care and education, benefiting more than 10,000 people in total. Between 2023 and 2024, we carried out targeted charitable projects in Hubei Province in the form of “early detection + follow-up + health education”. With a total investment of over RMB1.0 million, the projects served more than 3,000 residents. In 2024, leveraging our “IColocomf Colorectal Cancer Early Detection (艾長康結直腸癌早檢)”, we continuously conducted charitable cancer detection in Hubei Province, Tianjin Municipality and Hunan Province. The program cumulatively covered more than 10,000 people. From 2023 to 2025, we organized health lectures and campus educational campaigns in Hubei Province, reaching more than 5,000 people. Through platforms such as the Chu Merchants Conference (楚商大會), we promoted the “enterprise + foundation + community” cooperation model to advocate early detection and early treatment.

GOVERNANCE

Board Governance

To ensure professionalism in corporate management and independence in decision-making, we have carefully formed the Board of Directors with the diverse backgrounds, complementary capabilities and relevant experience. Three specialized committees have been established under the Board, namely the Remuneration Committee, the Nomination Committee and the Audit Committee. The Board of Directors consists of eight members, including three independent directors, two female directors and one director of Hong Kong nationality. Independent directors account for 37.50% of the Board, while female directors account for 25.00%. The backgrounds of the Board members span biomedicine, business management, marketing, investment and financial management. The integration of these diverse perspectives enhances the comprehensiveness of the Board’s decision-making and provides strong governance support for our steady development. For further details, please see “Directors and Senior Management” in this document.

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RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to the success of our business. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the Chinese and global medical device markets, our ability to develop, manufacture and commercialize our products and product candidates, and our ability to compete with other medical device companies. For details of various risks and uncertainties we face, please refer to “Risk Factors”. We also face various financial risks. In particular, we are exposed to credit, liquidity, interest rate and foreign exchange risks that may arise in the normal course of our business.

We have adopted a consolidated set of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an on-going basis. Our Audit Committee and ultimately our Directors supervise the implementation of our risk management policies. Risks identified by our management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors.

The following key principles outline our Group’s approach to risk management and internal control:

Our senior management oversees and manages the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) monitoring the most significant risks associated with our business operations and our management’s handling of such risks; and (iii) ensuring the appropriate application of our risk management framework across our Group.

Our legal and internal control personnel are responsible for developing and implementing our risk management policy and carrying out our day-to-day risk management practice, such as assessing risks on key business operations, advising risk responses and optimizing risk management policies. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

Intellectual Property Rights Risk Management

Compliance with applicable PRC and overseas laws and regulations, especially laws and regulations governing the protection of our intellectual property rights and the prevention of liabilities resulting from potential illegal content of publication and intellectual properties infringement are major focus areas of our operational risk management. Our legal department is responsible for approving contracts, monitoring any changes in the applicable laws and regulations and ensuring the ongoing compliance of our operations with the applicable law and regulations.

Our academic department assists in conducting searches to help ensure that all of our intellectual property is under the protection of relevant laws and regulations, and also helps ensure the application for trademark, copyright or patent registrations for, as well as filing with

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relevant authorities of, all of our products. The academic department shall then administer the execution process of obtaining the necessary filings, approvals, and/or licenses. Other than some standard contracts which have been reviewed and adopted by the legal department, all the contracts of our Company are required to be reviewed and approved by our legal department prior to execution. In addition, we establish policies for intellectual property infringement notices to help ensure timely monitoring the infringement incidents.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. During the Track Record Period, we regularly reviewed and enhanced our internal control system. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group’s internal control. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our operations, such as protection of intellectual property, environmental protection and occupational health and safety. We provide periodic training on these measures and procedures for our employees as part of our employee training program. We also regularly monitor the implementation of those measures and procedures through our on-site internal control team for each stage of the produce development process.
- Our Directors (who are responsible for monitoring the corporate governance of our Group), with assistance from our legal advisors, will periodically review our compliance status with all relevant laws and regulations upon Listing.
- Upon Listing, we will establish the Audit Committee which shall (i) make recommendations to our Directors on the appointment and removal of external auditors; and (ii) review the financial statements and render advice in respect of financial reporting as well as oversee the risk management and internal control procedures of our Group. For more details, please refer to “Directors and Senior Management – Board Committee – Audit Committee”.
- We will engage a compliance advisor to provide advice to our Directors and management team upon Listing regarding matters relating to the Listing Rules. Our compliance advisor is expected to, *inter alia*, ensure our use of the proceeds from the [REDACTED] complies with the section entitled “Future Plans and [REDACTED]” in this document after the Listing and provide support and advice regarding the requirements of relevant regulatory authorities on a timely basis.
- We will engage a PRC legal advisor to advise us on and keep us abreast with PRC laws and regulations upon Listing. We will continue to arrange various training to be provided by external legal advisors from time to time when necessary and/or any appropriate accredited institution to update our Directors, members of our senior management and relevant employees on the latest applicable laws and regulations.
- We maintain strict anti-corruption policies among our sales personnel and distributors in our sales and marketing activities. We have issued Anti-Fraud and Anti-Bribery Management Measures and Anti-Money Laundering Regulations, which clearly define the key areas and key steps of our anti-fraud function and the responsibilities and authorities of relevant departments in carrying out our anti-fraud function, and set up the internal protocols for reporting, investigation and remedy procedures, reporting channels and whistle-blower protection mechanisms. We also monitor our sales and marketing personnel to ensure their compliance with applicable promotion and

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advertising requirements, which include restrictions on promoting our products for unapproved uses or end-user populations, also known as off-label use, and limitations on industry-sponsored scientific and educational activities.

- We maintain a comprehensive treasury policy, detailing specific functions and internal control measures for capital use. These functions and measures include but are not limited to procedures of capital management, separation of capital management responsibilities, liquidity management and follow-up and analysis of the implementation of capital plan.
- Our Directors believe that compliance creates value for us. We are dedicated to cultivating a compliance culture among all of our employees. To ensure such compliance culture is embedded into everyday workflow and set the expectations for individual behaviour across our Group, we conduct regular internal compliance checks and inspections, adopt strict accountability internally and conduct compliance training.
- We will comply with the Corporate Governance Code. We have established three board committees, namely, the Audit Committee, the Remuneration Committee and the Nomination Committee, with respective terms of reference in compliance with the Corporate Governance Code. For details, please refer to the section headed “Directors and Senior Management”.
- We have adopted internal protocols governing both the confidentiality and privacy for patient sample and data. There is Standard Operation Procedure in place for sample/data collection, test procedures, data storage as well as data access. Such data access is on an as-needed basis for internal employees and requires written approvals from the head of the quality control/compliance department, and external access is not allowed.

LEGAL PROCEEDINGS AND NON-COMPLIANCE

Legal Proceedings

We may from time to time be involved in legal, arbitral or administrative proceedings arising in our ordinary operations. Our Directors confirmed that, as of the Latest Practicable Date, there was no legal, arbitral or administrative proceedings to which we were a party, individually or in aggregate that would have a material and adverse effect on our business, financial condition or results of operations and our Directors are not aware of any ongoing, potential or threatened legal, arbitral or administrative proceedings to which we were, or will be, named as a party that would have a material and adverse impact on our business, financial condition or results of operations. Our Directors further confirm that none of our Directors or senior management personnel was personally involved in any of these legal, arbitral or administrative proceedings which would have a material and adverse impact on our business, financial condition or results of operations.

Non-Compliance

During the Track Record Period and up to the Latest Practicable Date, we did not have any non-compliance incidents which our Directors believe would, individually or in the aggregate, have a material operational or financial impact on our business as a whole. As advised by our PRC Legal Advisors, during the Track Record Period and up to the Latest Practicable Date, we had complied with the applicable laws and regulations in all material respects.

LICENSES AND PERMITS

Our PRC Legal Advisors have advised, that as of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our business operations in the PRC. We had not experienced any material difficulty in renewing such licenses, permits, approvals and certificates during the Track Record Period and

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up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable. No material unexpected or adverse changes have occurred since the date of issue of the relevant regulatory approval for our Core Products.

License/Permit	Issuing Authority	Holder	First grant date	Latest grant date	Expiration date
Permit for the Medical Device Production (醫療器械生產許可證)	Hubei MPA	Our Company	March 31, 2022	August 26, 2025	March 30, 2027
Record-filing Proof for Production of Class I Medical Devices (第一類醫療器械生產備案憑證)	Wuhan AMR	Our Company	July 28, 2020	August 15, 2025	N/A
Record-filing Proof for Operation of Class II Medical Devices (第二類醫療器械經營備案憑證)	Wuhan East Lake High-tech Development Zone Administrative Committee (武漢東湖新技術開發區管理委員會)	Our Company	February 28, 2024	August 20, 2025	N/A
Registration Certificate for Medical Devices (In Vitro Diagnostic Reagents)	NMPA	Our Company	March 17, 2022	March 17, 2022	March 16, 2027
Registration Certificate for Medical Devices (In Vitro Diagnostic Reagents)	NMPA	Our Company	September 12, 2024	September 12, 2024	September 11, 2029
Registration Certificate for Medical Devices (In Vitro Diagnostic Reagents)	NMPA	Our Company	January 10, 2025	January 10, 2025	January 9, 2030
Registration Certificate for Medical Devices (In Vitro Diagnostic Reagents)	NMPA	Our Company	January 20, 2025	January 20, 2025	January 19, 2030
Registration Certificate for Medical Devices (In Vitro Diagnostic Reagents)	NMPA	Our Company	October 30, 2025	October 30, 2025	October 29, 2030
Medical device online sales filing (醫療器械網絡銷售備案)	Wuhan AMR	Our Company	May 23, 2024	May 23, 2024	N/A
Internet-based Medical Information Service Qualification Certificate (互聯網藥品信息服務資格證書)	Hubei MPA	Our Company	January 6, 2021	February 9, 2026	N/A
Customs Import and Export Consignee and Consignor Filing Record	Wuchang Customs	Our Company	February 9, 2022	February 9, 2022	N/A

BUSINESS

AWARDS AND RECOGNITION

During the Track Record Period, we have received awards and recognitions including, but are not limited to, the following:

Award/Recognition	Award Year	Awarding Institution/Authority
Hubei Province Small and Medium Enterprise Technology Center (湖北省中小企業技術中心)	2025	Hubei Province Economic and Information Technology Department (湖北省經濟和信息化廳)
Optics Valley 2024 Most Growth-Oriented Enterprise (光谷2024年度最具成長性企業)	2025	Wuhan East Lake High-tech Development Zone Committee of the CPC Wuhan Municipal Committee (中共武漢東湖新技術開發區工作委員會); Administration of Wuhan East Lake High-tech Development Zone (武漢東湖新技術開發區管理委員會)
2025 Optics Valley “Gazelle Select” Enterprise (2025年光谷“瞪羚精選”企業)	2025	Optics Valley Innovation Development Research Institute, Science and Innovation Bureau (光谷創新發展研究院、科創局)
Hubei Science and Innovation “Potential Unicorn” (湖北科創新物種“潛在獨角獸”)	2024	Hubei Province Science and Technology Department (湖北省科學技術廳)
Hubei Province “Contract-Honoring and Trustworthy” Enterprise (湖北省“守合同重信用”企業)	2024	Hubei Province Market Supervision Administration (湖北省市場監督管理局)
2024 Hubei Province Medical-Engineering Crossover Top 10 Innovation Achievements (2024年湖北省醫工交叉十大創新成果)	2024	Hubei Province Science and Technology Department (湖北省科學技術廳)
4th Excellence Award of Hubei Province High-Value Patent Competition (第四屆湖北省高價值專利大賽優秀獎)	2024	Hubei Province Intellectual Property Office (湖北省知識產權局)